

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
01/0102		ES	VISIT 1	2012-10-07	2012-10-08	Inclusion/Exclusion criteria not met
01/0103	ND basic	ES/SAF/FAS	VISIT 1	2012-10-17		
	ND basic	ES/SAF/FAS	VISIT 2A	2012-10-17		
	ND basic	ES/SAF/FAS	VISIT 2B	2012-10-18		
	ND basic	ES/SAF/FAS	VISIT 3A	2013-01-14		
	ND basic	ES/SAF/FAS	VISIT 3B	2013-01-15		
	ND basic	ES/SAF/FAS	VISIT 3K	2013-01-17		
	ND basic	ES/SAF/FAS	VISIT 3L	2013-02-04		
	ND basic	ES/SAF/FAS	VISIT 4	2013-02-20		
	ND basic	ES/SAF/FAS	VISIT 5	2013-04-17		
	ND basic	ES/SAF/FAS	VISIT 6	2013-07-18		
	ND basic	ES/SAF/FAS	VISIT 7	2014-01-08		
	ND basic	ES/SAF/FAS	VISIT 8	2015-02-16		
	ND basic	ES/SAF/FAS	VISIT 9	2016-02-10		
	ND basic	ES/SAF/FAS	VISIT 10	2017-01-12		
	ND basic	ES/SAF/FAS	VISIT 11	2018-01-17		
	ND basic	ES/SAF/FAS	END OF TRIAL			
01/0104	ND basic	ES/SAF/FAS	VISIT 1	2012-10-22		
	ND basic	ES/SAF/FAS	VISIT 2A	2012-10-23		
	ND basic	ES/SAF/FAS	VISIT 2B	2012-10-24		
	ND basic	ES/SAF/FAS	VISIT 3A	2013-01-21		
	ND basic	ES/SAF/FAS	VISIT 3B	2013-01-22		
	ND basic	ES/SAF/FAS	VISIT 3K	2013-01-24		
	ND basic	ES/SAF/FAS	VISIT 3L	2013-02-13		
	ND basic	ES/SAF/FAS	VISIT 4	2013-02-27		
	ND basic	ES/SAF/FAS	VISIT 5	2013-04-26		
	ND basic	ES/SAF/FAS	VISIT 6	2013-07-31		
	ND basic	ES/SAF/FAS	VISIT 7	2014-01-15		
	ND basic	ES/SAF/FAS	VISIT 8	2015-06-23		
	ND basic	ES/SAF/FAS	VISIT 9	2016-02-10		
	ND basic	ES/SAF/FAS	VISIT 10	2017-02-10		
	ND basic	ES/SAF/FAS	VISIT 11	2018-01-24		
	ND basic	ES/SAF/FAS	END OF TRIAL			
01/0105		ES	VISIT 1	2012-10-29	2012-10-29	Inclusion/Exclusion criteria not met

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Page 1 of 45

-continued on next page-

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
01/0106	ND plus	ES/SAF/FAS	VISIT 1	2012-11-26		
	ND plus	ES/SAF/FAS	VISIT 2A	2012-11-27		
	ND plus	ES/SAF/FAS	VISIT 2B	2012-11-28		
	ND plus	ES/SAF/FAS	VISIT 3A	2013-02-18		
	ND plus	ES/SAF/FAS	VISIT 3B	2013-02-19		
	ND plus	ES/SAF/FAS	VISIT 3K	2013-02-21		
	ND plus	ES/SAF/FAS	VISIT 3L	2013-03-13		
	ND plus	ES/SAF/FAS	VISIT 4	2013-04-03		
	ND plus	ES/SAF/FAS	VISIT 5	2013-05-22		
	ND plus	ES/SAF/FAS	VISIT 6	2013-08-21		
	ND plus	ES/SAF/FAS	VISIT 7	2014-02-19		
	ND plus	ES/SAF/FAS	VISIT 8	2015-02-18		
	ND plus	ES/SAF/FAS	VISIT 9	2016-02-24		
	ND plus	ES/SAF/FAS	VISIT 10	2017-02-11		
	ND plus	ES/SAF/FAS	VISIT 11	2018-02-14		
	ND plus	ES/SAF/FAS	END OF TRIAL			
01/0107	ND plus	ES/SAF/FAS	VISIT 1	2013-01-07		
	ND plus	ES/SAF/FAS	VISIT 2A	2013-01-08		
	ND plus	ES/SAF/FAS	VISIT 2B	2013-01-09		
	ND plus	ES/SAF/FAS	VISIT 3A	2013-04-08		
	ND plus	ES/SAF/FAS	VISIT 3B	2013-04-09		
	ND plus	ES/SAF/FAS	VISIT 3K	2013-04-11		
	ND plus	ES/SAF/FAS	VISIT 3L	2013-04-29		
	ND plus	ES/SAF/FAS	VISIT 4	2013-05-15		
	ND plus	ES/SAF/FAS	VISIT 5	2013-07-03		
	ND plus	ES/SAF/FAS	VISIT 6	2013-09-25		
	ND plus	ES/SAF/FAS	VISIT 7	2014-03-26		
	ND plus	ES/SAF/FAS	VISIT 8	2015-04-08		
	ND plus	ES/SAF/FAS	VISIT 9	2016-04-15		
	ND plus	ES/SAF/FAS	VISIT 10	2017-04-12		
	ND plus	ES/SAF/FAS	VISIT 11	2018-04-11		
	ND plus	ES/SAF/FAS	END OF TRIAL			
01/0108	ND plus	ES/SAF/FAS	VISIT 1	2013-01-09		
	ND plus	ES/SAF/FAS	VISIT 2A	2013-01-09		
	ND plus	ES/SAF/FAS	VISIT 2B	2013-01-10		
	ND plus	ES/SAF/FAS	VISIT 3A	2013-04-15		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
01/0108	ND plus	ES/SAF/FAS	VISIT 3B	2013-04-16		
	ND plus	ES/SAF/FAS	VISIT 3K	2013-04-18		
	ND plus	ES/SAF/FAS	VISIT 3L	2013-05-08		
	ND plus	ES/SAF/FAS	VISIT 4	2013-05-29		
	ND plus	ES/SAF/FAS	VISIT 5	2013-07-11		
	ND plus	ES/SAF/FAS	VISIT 6	2013-10-01		
	ND plus	ES/SAF/FAS	VISIT 7	2014-04-02		
	ND plus	ES/SAF/FAS	VISIT 8	2015-04-16		
	ND plus	ES/SAF/FAS	VISIT 9	2016-05-09		
	ND plus	ES/SAF/FAS	VISIT 10	2017-03-20		
	ND plus	ES/SAF/FAS	VISIT 11	2018-03-21		
	ND plus	ES/SAF/FAS	END OF TRIAL			
01/0109		ES	VISIT 1	2013-01-16	2013-01-16	Inclusion/Exclusion criteria not met
01/0110	ND basic	ES/SAF/FAS	VISIT 1	2013-01-22		
	ND basic	ES/SAF/FAS	VISIT 2A	2013-01-23		
	ND basic	ES/SAF/FAS	VISIT 2B	2013-01-24		
	ND basic	ES/SAF/FAS	VISIT 3A	2013-04-22		
	ND basic	ES/SAF/FAS	VISIT 3B	2013-04-23		
	ND basic	ES/SAF/FAS	VISIT 3K	2013-04-25		
	ND basic	ES/SAF/FAS	VISIT 3L	2013-05-15		
	ND basic	ES/SAF/FAS	VISIT 4	2013-06-05		
	ND basic	ES/SAF/FAS	VISIT 5	2013-07-31		
	ND basic	ES/SAF/FAS	VISIT 6	2013-10-15		
	ND basic	ES/SAF/FAS	VISIT 7	2014-04-09		
	ND basic	ES/SAF/FAS	VISIT 8	2015-04-22		
	ND basic	ES/SAF/FAS	VISIT 9	2016-05-09		
	ND basic	ES/SAF/FAS	VISIT 10	2017-04-24		
	ND basic	ES/SAF/FAS	VISIT 11	2018-03-28		
	ND basic	ES/SAF/FAS	END OF TRIAL			
01/0111	ND plus	ES/SAF/FAS	VISIT 1	2013-03-11		
	ND plus	ES/SAF/FAS	VISIT 2A	2013-03-11		
	ND plus	ES/SAF/FAS	VISIT 2B	2013-03-12		
	ND plus	ES/SAF/FAS	VISIT 3A	2013-06-10		
	ND plus	ES/SAF/FAS	VISIT 3B	2013-06-11		
	ND plus	ES/SAF/FAS	VISIT 3K	2013-06-13		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
01/0111	ND plus	ES/SAF/FAS	VISIT 3L	2013-07-02		
	ND plus	ES/SAF/FAS	VISIT 4	2013-07-25		
	ND plus	ES/SAF/FAS	VISIT 5	2013-09-04		
	ND plus	ES/SAF/FAS	VISIT 6	2013-12-18		
	ND plus	ES/SAF/FAS	VISIT 7	2014-06-04		
	ND plus	ES/SAF/FAS	VISIT 8	2015-06-10		
	ND plus	ES/SAF/FAS	VISIT 9	2016-06-20		
	ND plus	ES/SAF/FAS	VISIT 10	2017-06-27		
	ND plus	ES/SAF/FAS	VISIT 11	2018-05-30		
01/0112	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND basic	ES/SAF	VISIT 1	2013-03-25		
	ND basic	ES/SAF	VISIT 2A	2013-03-26		
	ND basic	ES/SAF	VISIT 2B	2013-03-26		
	ND basic	ES/SAF	VISIT 3B	2013-04-01		
	ND basic	ES/SAF	VISIT 11	2013-07-08		
	ND basic	ES/SAF	END OF TRIAL		2013-04-02	Inclusion/Exclusion criteria not met recurrent disc hernation after surgery and prior transplantation
	ND basic	ES/SAF	UNSCHEDULED	2013-04-02		
01/0113	ND basic	ES/SAF/FAS	VISIT 1	2013-05-22		
	ND basic	ES/SAF/FAS	VISIT 2A	2013-05-22		
	ND basic	ES/SAF/FAS	VISIT 2B	2013-05-23		
	ND basic	ES/SAF/FAS	VISIT 3A	2013-08-05		
	ND basic	ES/SAF/FAS	VISIT 3B	2013-08-06		
	ND basic	ES/SAF/FAS	VISIT 3K	2013-08-08		
	ND basic	ES/SAF/FAS	VISIT 3L	2013-08-28		
	ND basic	ES/SAF/FAS	VISIT 4	2013-09-10		
	ND basic	ES/SAF/FAS	VISIT 5	2013-11-06		
	ND basic	ES/SAF/FAS	VISIT 6	2014-01-28		
	ND basic	ES/SAF/FAS	VISIT 7	2014-07-30		
	ND basic	ES/SAF/FAS	VISIT 8	2015-07-22		
	ND basic	ES/SAF/FAS	VISIT 9	2016-08-22		
	ND basic	ES/SAF/FAS	VISIT 10	2017-07-26		
	ND basic	ES/SAF/FAS	VISIT 11	2018-10-17		
	ND basic	ES/SAF/FAS	END OF TRIAL			
	ND basic	ES/SAF/FAS	UNSCHEDULED	2014-07-11		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
01/0113	ND basic	ES/SAF/FAS	UNSCHEDULED	2014-08-04		
	ND basic	ES/SAF/FAS	UNSCHEDULED	2014-09-03		
	ND basic	ES/SAF/FAS	UNSCHEDULED	2014-10-02		
01/0114	ND basic	ES/SAF/FAS	VISIT 1	2013-06-09		
	ND basic	ES/SAF/FAS	VISIT 2A	2013-06-10		
	ND basic	ES/SAF/FAS	VISIT 2B	2013-06-11		
	ND basic	ES/SAF/FAS	VISIT 3A	2013-09-10		
	ND basic	ES/SAF/FAS	VISIT 3B	2013-09-11		
	ND basic	ES/SAF/FAS	VISIT 3K	2013-09-13		
	ND basic	ES/SAF/FAS	VISIT 3L	2013-10-01		
	ND basic	ES/SAF/FAS	VISIT 4	2013-10-16		
	ND basic	ES/SAF/FAS	VISIT 5	2013-12-10		
	ND basic	ES/SAF/FAS	VISIT 6	2014-03-12		
	ND basic	ES/SAF/FAS	VISIT 7	2014-09-10		
	ND basic	ES/SAF/FAS	VISIT 8	2015-09-09		
	ND basic	ES/SAF/FAS	VISIT 9	2016-08-22		
	ND basic	ES/SAF/FAS	VISIT 10	2017-08-23		
	ND basic	ES/SAF/FAS	VISIT 11	2018-09-05		
	ND basic	ES/SAF/FAS	END OF TRIAL			
01/0115	ND plus	ES/SAF/FAS	VISIT 1	2013-06-11		
	ND plus	ES/SAF/FAS	VISIT 2A	2013-06-11		
	ND plus	ES/SAF/FAS	VISIT 2B	2013-06-12		
	ND plus	ES/SAF/FAS	VISIT 3A	2013-09-16		
	ND plus	ES/SAF/FAS	VISIT 3B	2013-09-17		
	ND plus	ES/SAF/FAS	VISIT 3K	2013-09-19		
	ND plus	ES/SAF/FAS	VISIT 3L	2013-10-08		
	ND plus	ES/SAF/FAS	VISIT 4	2013-10-30		
	ND plus	ES/SAF/FAS	VISIT 5	2013-12-12		
	ND plus	ES/SAF/FAS	VISIT 6	2014-03-11		
	ND plus	ES/SAF/FAS	VISIT 7	2014-09-25		
	ND plus	ES/SAF/FAS	VISIT 8	2015-09-16		
	ND plus	ES/SAF/FAS	VISIT 9	2016-11-23		
	ND plus	ES/SAF/FAS	VISIT 10	2017-08-21		
	ND plus	ES/SAF/FAS	VISIT 11	2018-10-10		
	ND plus	ES/SAF/FAS	END OF TRIAL			

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
01/0116	ND basic	ES/SAF	VISIT 1	2013-06-17		
	ND basic	ES/SAF	VISIT 2A	2013-06-17		
	ND basic	ES/SAF	VISIT 2B	2013-06-18		
	ND basic	ES/SAF	END OF TRIAL		2013-06-18	Inclusion/Exclusion criteria not met Exclusion criteria No 7 became known after AE
01/0117		ES	VISIT 1	2013-06-18	2013-06-19	Withdrawal of clinical trial subject's consent
01/0118	ND plus	ES/SAF/FAS	VISIT 1	2013-07-08		
	ND plus	ES/SAF/FAS	VISIT 2A	2013-07-09		
	ND plus	ES/SAF/FAS	VISIT 2B	2013-07-10		
	ND plus	ES/SAF/FAS	VISIT 3A	2013-10-07		
	ND plus	ES/SAF/FAS	VISIT 3B	2013-10-08		
	ND plus	ES/SAF/FAS	VISIT 3K	2013-10-10		
	ND plus	ES/SAF/FAS	VISIT 3L	2013-10-30		
	ND plus	ES/SAF/FAS	VISIT 4	2013-11-20		
	ND plus	ES/SAF/FAS	VISIT 5	2014-01-07		
	ND plus	ES/SAF/FAS	VISIT 6	2014-03-25		
	ND plus	ES/SAF/FAS	VISIT 7	2014-10-08		
	ND plus	ES/SAF/FAS	VISIT 8	2015-10-07		
	ND plus	ES/SAF/FAS	VISIT 9	2016-11-04		
	ND plus	ES/SAF/FAS	VISIT 10	2017-10-31		
	ND plus	ES/SAF/FAS	VISIT 11	2018-10-03		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2014-05-28		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2014-07-09		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2014-08-20		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2014-09-18		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2014-10-22		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2016-06-15		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2016-05-25		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2018-02-01		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2018-01-16		
01/0119	ND basic	ES/SAF/FAS	VISIT 1	2013-07-22		
	ND basic	ES/SAF/FAS	VISIT 2A	2013-07-22		
	ND basic	ES/SAF/FAS	VISIT 2B	2013-07-23		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
01/0119	ND basic	ES/SAF/FAS	VISIT 3A	2013-10-14		
	ND basic	ES/SAF/FAS	VISIT 3B	2013-10-15		
	ND basic	ES/SAF/FAS	VISIT 3K	2013-10-17		
	ND basic	ES/SAF/FAS	VISIT 3L	2013-11-06		
	ND basic	ES/SAF/FAS	VISIT 4	2013-11-19		
	ND basic	ES/SAF/FAS	VISIT 5	2014-01-14		
	ND basic	ES/SAF/FAS	VISIT 6	2014-04-03		
	ND basic	ES/SAF/FAS	VISIT 7	2014-10-15		
	ND basic	ES/SAF/FAS	VISIT 8	2015-10-14		
	ND basic	ES/SAF/FAS	VISIT 9	2016-11-04		
	ND basic	ES/SAF/FAS	VISIT 10	2017-10-11		
	ND basic	ES/SAF/FAS	VISIT 11	2018-10-10		
	ND basic	ES/SAF/FAS	END OF TRIAL			
	ND basic	ES/SAF/FAS	UNSCHEDULED	2014-07-14		
01/0120		ES	VISIT 1	2013-07-25	2013-07-29	Inclusion/Exclusion criteria not met
01/0121	ND plus	ES/SAF/FAS	VISIT 1	2013-09-18		
	ND plus	ES/SAF/FAS	VISIT 2A	2013-10-14		
	ND plus	ES/SAF/FAS	VISIT 2B	2013-10-15		
	ND plus	ES/SAF/FAS	VISIT 3A	2014-01-13		
	ND plus	ES/SAF/FAS	VISIT 3B	2014-01-14		
	ND plus	ES/SAF/FAS	VISIT 3K	2014-01-16		
	ND plus	ES/SAF/FAS	VISIT 3L	2014-02-05		
	ND plus	ES/SAF/FAS	VISIT 4	2014-02-18		
	ND plus	ES/SAF/FAS	VISIT 5	2014-04-08		
	ND plus	ES/SAF/FAS	VISIT 6	2014-07-14		
	ND plus	ES/SAF/FAS	VISIT 7	2015-01-21		
	ND plus	ES/SAF/FAS	VISIT 8	2016-01-13		
	ND plus	ES/SAF/FAS	VISIT 9	2016-12-28		
	ND plus	ES/SAF/FAS	END OF TRIAL		2016-12-28	Other reason
01/0122	ND plus	ES/SAF/FAS	VISIT 1	2013-09-25		
	ND plus	ES/SAF/FAS	VISIT 2A	2013-09-25		
	ND plus	ES/SAF/FAS	VISIT 2B	2013-09-26		
	ND plus	ES/SAF/FAS	VISIT 3A	2013-12-16		
	ND plus	ES/SAF/FAS	VISIT 3B	2013-12-17		
	ND plus	ES/SAF/FAS	VISIT 3K	2013-12-19		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
01/0122	ND plus	ES/SAF/FAS	VISIT 3L	2014-01-09		
	ND plus	ES/SAF/FAS	VISIT 4	2014-01-29		
	ND plus	ES/SAF/FAS	VISIT 5	2014-03-18		
	ND plus	ES/SAF/FAS	VISIT 6	2014-06-11		
	ND plus	ES/SAF/FAS	VISIT 7	2014-12-17		
	ND plus	ES/SAF/FAS	VISIT 8	2015-12-16		
	ND plus	ES/SAF/FAS	VISIT 9	2016-12-28		
	ND plus	ES/SAF/FAS	VISIT 10	2017-12-11		
	ND plus	ES/SAF/FAS	VISIT 11	2018-12-19		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2016-06-15		
01/0123	ND plus	ES/SAF/FAS	VISIT 1	2014-09-15		
	ND plus	ES/SAF/FAS	VISIT 2A	2014-09-15		
	ND plus	ES/SAF/FAS	VISIT 2B	2014-09-16		
	ND plus	ES/SAF/FAS	VISIT 3A	2014-12-18		
	ND plus	ES/SAF/FAS	VISIT 3B	2014-12-19		
	ND plus	ES/SAF/FAS	VISIT 4	2015-01-28		
	ND plus	ES/SAF/FAS	VISIT 5	2015-03-20		
	ND plus	ES/SAF/FAS	VISIT 6	2015-07-02		
	ND plus	ES/SAF/FAS	VISIT 7	2015-12-17		
	ND plus	ES/SAF/FAS	VISIT 8	2016-12-07		
	ND plus	ES/SAF/FAS	VISIT 9	2017-12-06		
	ND plus	ES/SAF/FAS	VISIT 10	2018-12-12		
	ND plus	ES/SAF/FAS	END OF TRIAL		2020-07-21	Other reason
	ND plus	ES/SAF/FAS	UNSCHEDULED	2017-02-10		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2017-03-06		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2017-06-09		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2018-05-24		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2020-07-21		
01/0124	ND plus	ES/SAF	VISIT 1	2014-10-01		
	ND plus	ES/SAF	VISIT 2A	2014-11-05		
	ND plus	ES/SAF	VISIT 2B	2014-11-06		
	ND plus	ES/SAF	END OF TRIAL		2015-01-22	Withdrawal of clinical trial subject's consent
01/0125	SC	ES/SAF/FAS	VISIT 1	2014-10-06		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
01/0125	SC	ES/SAF/FAS	VISIT 2A	2014-10-06		
	SC	ES/SAF/FAS	VISIT 2B	2014-10-07		
	SC	ES/SAF/FAS	VISIT 4	2014-11-19		
	SC	ES/SAF/FAS	VISIT 5	2015-01-07		
	SC	ES/SAF/FAS	VISIT 6	2015-03-25		
	SC	ES/SAF/FAS	VISIT 7	2015-09-30		
	SC	ES/SAF/FAS	VISIT 8	2016-09-28		
	SC	ES/SAF/FAS	VISIT 9	2017-10-06		
	SC	ES/SAF/FAS	VISIT 10	2018-09-12		
	SC	ES/SAF/FAS	VISIT 11	2019-10-02		
	SC	ES/SAF/FAS	END OF TRIAL			
	SC	ES/SAF/FAS	UNSCHEDULED	2018-01-10		
01/0126	ND basic	ES/SAF/FAS	VISIT 1	2014-10-06		
	ND basic	ES/SAF/FAS	VISIT 2A	2014-10-07		
	ND basic	ES/SAF/FAS	VISIT 2B	2014-10-08		
	ND basic	ES/SAF/FAS	VISIT 3A	2015-01-07		
	ND basic	ES/SAF/FAS	VISIT 3B	2015-01-08		
	ND basic	ES/SAF/FAS	VISIT 4	2015-02-16		
	ND basic	ES/SAF/FAS	VISIT 5	2015-04-08		
	ND basic	ES/SAF/FAS	VISIT 6	2015-06-30		
	ND basic	ES/SAF/FAS	VISIT 7	2016-01-12		
	ND basic	ES/SAF/FAS	VISIT 8	2017-01-11		
	ND basic	ES/SAF/FAS	VISIT 9	2018-01-16		
	ND basic	ES/SAF/FAS	VISIT 10	2019-01-09		
	ND basic	ES/SAF/FAS	VISIT 11	2019-12-11		
	ND basic	ES/SAF/FAS	END OF TRIAL			
	ND basic	ES/SAF/FAS	UNSCHEDULED	2015-03-04		
01/0127	ND plus	ES/SAF/FAS	VISIT 1	2014-10-17		
	ND plus	ES/SAF/FAS	VISIT 2A	2014-10-19		
	ND plus	ES/SAF/FAS	VISIT 2B	2014-10-20		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-01-08		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-01-09		
	ND plus	ES/SAF/FAS	VISIT 4	2015-02-19		
	ND plus	ES/SAF/FAS	VISIT 5	2015-04-08		
	ND plus	ES/SAF/FAS	VISIT 6	2015-07-01		
	ND plus	ES/SAF/FAS	VISIT 7	2016-01-13		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
01/0127	ND plus	ES/SAF/FAS	VISIT 8	2017-01-11		
	ND plus	ES/SAF/FAS	VISIT 9	2018-01-08		
	ND plus	ES/SAF/FAS	VISIT 10	2019-01-09		
	ND plus	ES/SAF/FAS	VISIT 11	2019-12-18		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2018-02-14		
01/0128	ND plus	ES/SAF/FAS	VISIT 1	2014-10-20		
	ND plus	ES/SAF/FAS	VISIT 2A	2014-10-21		
	ND plus	ES/SAF/FAS	VISIT 2B	2014-10-21		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-01-12		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-01-13		
	ND plus	ES/SAF/FAS	VISIT 4	2015-02-24		
	ND plus	ES/SAF/FAS	VISIT 5	2015-04-14		
	ND plus	ES/SAF/FAS	VISIT 6	2015-07-14		
	ND plus	ES/SAF/FAS	VISIT 7	2016-01-14		
	ND plus	ES/SAF/FAS	VISIT 8	2017-01-25		
	ND plus	ES/SAF/FAS	VISIT 9	2018-01-24		
	ND plus	ES/SAF/FAS	VISIT 10	2019-01-25		
	ND plus	ES/SAF/FAS	VISIT 11	2019-12-18		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2019-03-01		
01/0129	SC	ES/SAF/FAS	VISIT 1	2014-10-28		
	SC	ES/SAF/FAS	VISIT 2A	2014-10-28		
	SC	ES/SAF/FAS	VISIT 2B	2014-10-29		
	SC	ES/SAF/FAS	VISIT 4	2014-12-10		
	SC	ES/SAF/FAS	VISIT 5	2015-01-21		
	SC	ES/SAF/FAS	VISIT 6	2015-04-14		
	SC	ES/SAF/FAS	VISIT 7	2015-10-21		
	SC	ES/SAF/FAS	VISIT 8	2016-10-05		
	SC	ES/SAF/FAS	VISIT 9	2017-10-04		
	SC	ES/SAF/FAS	VISIT 10	2019-01-16		
	SC	ES/SAF/FAS	VISIT 11	2019-10-02		
	SC	ES/SAF/FAS	END OF TRIAL			
	SC	ES/SAF/FAS	UNSCHEDULED	2019-02-15		
	SC	ES/SAF/FAS	UNSCHEDULED	2019-03-18		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
01/0130	ND basic	ES/SAF/FAS	VISIT 1	2014-11-19		
	ND basic	ES/SAF/FAS	VISIT 2A	2014-11-19		
	ND basic	ES/SAF/FAS	VISIT 2B	2014-11-20		
	ND basic	ES/SAF/FAS	VISIT 3A	2015-02-03		
	ND basic	ES/SAF/FAS	VISIT 3B	2015-02-03		
	ND basic	ES/SAF/FAS	VISIT 4	2015-03-17		
	ND basic	ES/SAF/FAS	VISIT 5	2015-04-27		
	ND basic	ES/SAF/FAS	VISIT 6	2015-07-29		
	ND basic	ES/SAF/FAS	VISIT 7	2016-01-20		
	ND basic	ES/SAF/FAS	VISIT 8	2017-02-01		
	ND basic	ES/SAF/FAS	VISIT 9	2018-01-31		
	ND basic	ES/SAF/FAS	VISIT 10	2019-02-13		
	ND basic	ES/SAF/FAS	VISIT 11	2020-01-22		
	ND basic	ES/SAF/FAS	END OF TRIAL			
01/0131	ND plus	ES/SAF/FAS	VISIT 1	2014-11-28		
	ND plus	ES/SAF/FAS	VISIT 2A	2014-11-30		
	ND plus	ES/SAF/FAS	VISIT 2B	2014-12-01		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-02-18		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-02-19		
	ND plus	ES/SAF/FAS	VISIT 4	2015-04-09		
	ND plus	ES/SAF/FAS	VISIT 5	2015-05-27		
	ND plus	ES/SAF/FAS	VISIT 6	2015-08-18		
	ND plus	ES/SAF/FAS	VISIT 7	2016-02-18		
	ND plus	ES/SAF/FAS	VISIT 8	2017-03-15		
	ND plus	ES/SAF/FAS	VISIT 9	2018-01-24		
	ND plus	ES/SAF/FAS	VISIT 10	2019-01-28		
	ND plus	ES/SAF/FAS	VISIT 11	2020-01-29		
	ND plus	ES/SAF/FAS	END OF TRIAL			
01/0132	SC	ES/SAF/FAS	VISIT 1	2014-12-01		
	SC	ES/SAF/FAS	VISIT 2A	2014-12-01		
	SC	ES/SAF/FAS	VISIT 2B	2014-12-02		
	SC	ES/SAF/FAS	VISIT 4	2015-01-13		
	SC	ES/SAF/FAS	VISIT 5	2015-03-18		
	SC	ES/SAF/FAS	VISIT 6	2015-05-20		
	SC	ES/SAF/FAS	VISIT 7	2015-11-25		
	SC	ES/SAF/FAS	VISIT 8	2016-11-23		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Page 11 of 45

-continued on next page-

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation	
01/0132	SC	ES/SAF/FAS	VISIT 9	2017-11-27			
	SC	ES/SAF/FAS	VISIT 10	2018-12-27			
	SC	ES/SAF/FAS	VISIT 11	2019-11-20			
	SC	ES/SAF/FAS	END OF TRIAL				
01/0133	ND plus	ES/SAF	VISIT 1	2014-12-15			
	ND plus	ES/SAF	VISIT 2A	2014-12-15			
	ND plus	ES/SAF	VISIT 2B	2014-12-16			
	ND plus	ES/SAF	END OF TRIAL		2014-12-30	Inclusion/Exclusion criteria not met	REHERNIATION BEFORE VISIT 3
	ND plus	ES/SAF	UNSCHEDULED	2014-12-29			
01/0134	ND basic	ES/SAF	VISIT 1	2014-12-16			
	ND basic	ES/SAF	VISIT 2A	2014-12-16			
	ND basic	ES/SAF	VISIT 2B	2014-12-17			
	ND basic	ES/SAF	END OF TRIAL		2015-03-09	Withdrawal of clinical trial subject's consent	
	ND basic	ES/SAF	UNSCHEDULED	2015-01-15			
01/0135	ND plus	ES/SAF/FAS	VISIT 1	2015-01-14			
	ND plus	ES/SAF/FAS	VISIT 2A	2015-01-14			
	ND plus	ES/SAF/FAS	VISIT 2B	2015-01-15			
	ND plus	ES/SAF/FAS	VISIT 3A	2015-04-07			
	ND plus	ES/SAF/FAS	VISIT 3B	2015-04-08			
	ND plus	ES/SAF/FAS	VISIT 4	2015-05-26			
	ND plus	ES/SAF/FAS	VISIT 5	2015-07-07			
	ND plus	ES/SAF/FAS	VISIT 6	2015-10-06			
	ND plus	ES/SAF/FAS	VISIT 7	2016-04-06			
	ND plus	ES/SAF/FAS	VISIT 8	2017-05-03			
	ND plus	ES/SAF/FAS	VISIT 9	2018-04-13			
	ND plus	ES/SAF/FAS	VISIT 10	2019-05-14			
	ND plus	ES/SAF/FAS	VISIT 11	2020-05-27			
	ND plus	ES/SAF/FAS	END OF TRIAL				
01/0136	ND basic	ES/SAF/FAS	VISIT 1	2015-02-20			
	ND basic	ES/SAF/FAS	VISIT 2A	2015-02-22			
	ND basic	ES/SAF/FAS	VISIT 2B	2015-02-23			
	ND basic	ES/SAF/FAS	VISIT 3A	2015-06-02			
	ND basic	ES/SAF/FAS	VISIT 3B	2015-06-02			

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
01/0136	ND basic	ES/SAF/FAS	VISIT 4	2015-07-15		
	ND basic	ES/SAF/FAS	VISIT 5	2015-08-26		
	ND basic	ES/SAF/FAS	VISIT 6	2015-11-24		
	ND basic	ES/SAF/FAS	VISIT 7	2016-05-25		
	ND basic	ES/SAF/FAS	VISIT 8	2017-06-06		
	ND basic	ES/SAF/FAS	VISIT 9	2018-05-23		
	ND basic	ES/SAF/FAS	VISIT 10	2019-06-06		
	ND basic	ES/SAF/FAS	VISIT 11	2020-06-10		
	ND basic	ES/SAF/FAS	END OF TRIAL			
01/0137	ND plus	ES/SAF/FAS	UNSCHEDULED	2015-10-21		
	ND plus	ES/SAF/FAS	VISIT 1	2015-02-25		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-02-25		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-02-26		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-06-01		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-06-02		
	ND plus	ES/SAF/FAS	VISIT 4	2015-07-16		
	ND plus	ES/SAF/FAS	VISIT 5	2015-08-25		
	ND plus	ES/SAF/FAS	VISIT 6	2015-11-18		
	ND plus	ES/SAF/FAS	VISIT 7	2016-06-01		
	ND plus	ES/SAF/FAS	VISIT 8	2017-06-07		
	ND plus	ES/SAF/FAS	VISIT 9	2018-06-06		
	ND plus	ES/SAF/FAS	VISIT 10	2019-06-06		
	ND plus	ES/SAF/FAS	VISIT 11	2020-06-24		
	ND plus	ES/SAF/FAS	END OF TRIAL			
01/0138	SC	ES/SAF/FAS	VISIT 1	2015-03-05		
	SC	ES/SAF/FAS	VISIT 2A	2015-03-08		
	SC	ES/SAF/FAS	VISIT 2B	2015-03-09		
	SC	ES/SAF/FAS	VISIT 4	2015-04-23		
	SC	ES/SAF/FAS	VISIT 5	2015-06-05		
	SC	ES/SAF/FAS	VISIT 6	2015-09-15		
	SC	ES/SAF/FAS	VISIT 7	2016-02-24		
	SC	ES/SAF/FAS	VISIT 8	2017-02-08		
	SC	ES/SAF/FAS	VISIT 9	2018-02-07		
	SC	ES/SAF/FAS	VISIT 10	2019-02-13		
	SC	ES/SAF/FAS	VISIT 11	2020-02-12		
	SC	ES/SAF/FAS	END OF TRIAL			

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
01/0139	ND plus	ES/SAF/FAS	VISIT 1	2015-03-09		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-03-09		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-03-10		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-06-02		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-06-03		
	ND plus	ES/SAF/FAS	VISIT 4	2015-07-14		
	ND plus	ES/SAF/FAS	VISIT 5	2015-08-26		
	ND plus	ES/SAF/FAS	VISIT 6	2015-12-02		
	ND plus	ES/SAF/FAS	VISIT 7	2016-06-15		
	ND plus	ES/SAF/FAS	VISIT 8	2017-06-07		
	ND plus	ES/SAF/FAS	VISIT 9	2018-06-06		
	ND plus	ES/SAF/FAS	VISIT 10	2019-06-13		
	ND plus	ES/SAF/FAS	END OF TRIAL		2019-06-13	Other reason
	ND plus	ES/SAF/FAS	UNSCHEDULED	2016-12-21		
01/0140	ND basic	ES/SAF/FAS	VISIT 1	2015-05-11		
	ND basic	ES/SAF/FAS	VISIT 2A	2015-05-12		
	ND basic	ES/SAF/FAS	VISIT 2B	2015-05-12		
	ND basic	ES/SAF/FAS	VISIT 3A	2015-08-10		
	ND basic	ES/SAF/FAS	VISIT 3B	2015-08-11		
	ND basic	ES/SAF/FAS	VISIT 4	2015-09-22		
	ND basic	ES/SAF/FAS	VISIT 5	2015-11-04		
	ND basic	ES/SAF/FAS	VISIT 6	2016-02-08		
	ND basic	ES/SAF/FAS	VISIT 7	2016-07-27		
	ND basic	ES/SAF/FAS	VISIT 8	2017-07-26		
	ND basic	ES/SAF/FAS	VISIT 9	2018-07-25		
	ND basic	ES/SAF/FAS	VISIT 10	2019-07-31		
	ND basic	ES/SAF/FAS	VISIT 11	2020-08-19		
	ND basic	ES/SAF/FAS	END OF TRIAL			
01/0141	SC	ES/SAF/FAS	VISIT 1	2015-05-21		
	SC	ES/SAF/FAS	VISIT 2A	2015-05-26		
	SC	ES/SAF/FAS	VISIT 2B	2015-05-27		
	SC	ES/SAF/FAS	VISIT 4	2015-07-13		
	SC	ES/SAF/FAS	VISIT 5	2015-09-02		
	SC	ES/SAF/FAS	VISIT 6	2015-11-11		
	SC	ES/SAF/FAS	VISIT 7	2016-05-18		
	SC	ES/SAF/FAS	VISIT 8	2017-05-10		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Page 14 of 45

-continued on next page-

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
01/0141	SC	ES/SAF/FAS	VISIT 9	2018-04-26		
	SC	ES/SAF/FAS	VISIT 10	2019-05-13		
	SC	ES/SAF/FAS	VISIT 11	2020-06-24		
	SC	ES/SAF/FAS	END OF TRIAL			
	SC	ES/SAF/FAS	UNSCHEDULED	2021-03-03		
01/0142	ND plus	ES/SAF/FAS	VISIT 1	2015-05-26		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-05-27		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-05-27		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-08-24		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-08-25		
	ND plus	ES/SAF/FAS	VISIT 4	2015-10-05		
	ND plus	ES/SAF/FAS	VISIT 5	2015-11-25		
	ND plus	ES/SAF/FAS	VISIT 6	2016-03-02		
	ND plus	ES/SAF/FAS	VISIT 7	2016-08-31		
	ND plus	ES/SAF/FAS	VISIT 8	2017-08-30		
	ND plus	ES/SAF/FAS	VISIT 9	2018-08-22		
	ND plus	ES/SAF/FAS	VISIT 10	2019-09-03		
	ND plus	ES/SAF/FAS	VISIT 11	2020-08-05		
	ND plus	ES/SAF/FAS	END OF TRIAL			
01/0143	ND plus	ES/SAF/FAS	VISIT 1	2015-06-15		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-06-16		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-06-17		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-09-22		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-09-22		
	ND plus	ES/SAF/FAS	VISIT 4	2015-11-02		
	ND plus	ES/SAF/FAS	VISIT 5	2015-12-16		
	ND plus	ES/SAF/FAS	VISIT 6	2016-03-09		
	ND plus	ES/SAF/FAS	VISIT 7	2016-09-07		
	ND plus	ES/SAF/FAS	VISIT 8	2017-08-23		
	ND plus	ES/SAF/FAS	VISIT 9	2018-08-22		
	ND plus	ES/SAF/FAS	VISIT 10	2019-08-22		
	ND plus	ES/SAF/FAS	VISIT 11	2020-09-16		
	ND plus	ES/SAF/FAS	END OF TRIAL			
01/0144	ND basic	ES/SAF/FAS	VISIT 1	2015-06-22		
	ND basic	ES/SAF/FAS	VISIT 2A	2015-06-23		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Page 15 of 45

-continued on next page-

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
01/0144	ND basic	ES/SAF/FAS	VISIT 2B	2015-06-24		
	ND basic	ES/SAF/FAS	VISIT 3A	2015-09-22		
	ND basic	ES/SAF/FAS	VISIT 3B	2015-09-22		
	ND basic	ES/SAF/FAS	VISIT 4	2015-11-03		
	ND basic	ES/SAF/FAS	VISIT 5	2015-12-17		
	ND basic	ES/SAF/FAS	VISIT 6	2016-03-30		
	ND basic	ES/SAF/FAS	VISIT 7	2016-09-21		
	ND basic	ES/SAF/FAS	VISIT 8	2017-08-30		
	ND basic	ES/SAF/FAS	VISIT 9	2018-08-22		
	ND basic	ES/SAF/FAS	VISIT 10	2019-09-02		
	ND basic	ES/SAF/FAS	VISIT 11	2020-09-09		
	ND basic	ES/SAF/FAS	END OF TRIAL			
	ND basic	ES/SAF/FAS	UNSCHEDULED	2019-01-23		
	ND basic	ES/SAF/FAS	UNSCHEDULED	2019-05-23		
01/0145	ND plus	ES/SAF/FAS	VISIT 1	2015-07-14		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-07-15		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-07-16		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-10-05		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-10-07		
	ND plus	ES/SAF/FAS	VISIT 4	2015-11-19		
	ND plus	ES/SAF/FAS	VISIT 5	2016-01-05		
	ND plus	ES/SAF/FAS	VISIT 6	2016-04-05		
	ND plus	ES/SAF/FAS	VISIT 7	2016-10-05		
	ND plus	ES/SAF/FAS	VISIT 8	2017-09-20		
	ND plus	ES/SAF/FAS	VISIT 9	2018-09-12		
	ND plus	ES/SAF/FAS	VISIT 10	2019-12-06		
	ND plus	ES/SAF/FAS	VISIT 11	2020-09-30		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2015-09-14		
01/0146	SC	ES/SAF/FAS	VISIT 1	2015-07-15		
	SC	ES/SAF/FAS	VISIT 2A	2015-07-15		
	SC	ES/SAF/FAS	VISIT 2B	2015-07-16		
	SC	ES/SAF/FAS	VISIT 4	2015-08-27		
	SC	ES/SAF/FAS	VISIT 5	2015-10-13		
	SC	ES/SAF/FAS	VISIT 6	2016-01-19		
	SC	ES/SAF/FAS	VISIT 7	2016-07-06		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Page 16 of 45

-continued on next page-

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
01/0146	SC	ES/SAF/FAS	VISIT 8	2017-06-21		
	SC	ES/SAF/FAS	VISIT 9	2018-06-20		
	SC	ES/SAF/FAS	VISIT 10	2019-06-06		
	SC	ES/SAF/FAS	VISIT 11	2020-08-26		
	SC	ES/SAF/FAS	END OF TRIAL			
01/0147	ND plus	ES/SAF/FAS	VISIT 1	2015-08-19		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-08-19		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-08-20		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-11-17		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-11-18		
	ND plus	ES/SAF/FAS	VISIT 4	2016-01-05		
	ND plus	ES/SAF/FAS	VISIT 5	2016-02-09		
	ND plus	ES/SAF/FAS	VISIT 6	2016-05-11		
	ND plus	ES/SAF/FAS	VISIT 7	2016-11-16		
	ND plus	ES/SAF/FAS	VISIT 8	2017-11-15		
	ND plus	ES/SAF/FAS	VISIT 9	2018-11-19		
	ND plus	ES/SAF/FAS	VISIT 10	2019-12-02		
	ND plus	ES/SAF/FAS	VISIT 11	2020-11-04		
	ND plus	ES/SAF/FAS	END OF TRIAL			
01/0148	ND plus	ES/SAF/FAS	VISIT 1	2015-10-21		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-10-21		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-10-22		
	ND plus	ES/SAF/FAS	VISIT 3A	2016-01-11		
	ND plus	ES/SAF/FAS	VISIT 3B	2016-01-12		
	ND plus	ES/SAF/FAS	VISIT 4	2016-02-24		
	ND plus	ES/SAF/FAS	VISIT 5	2016-04-13		
	ND plus	ES/SAF/FAS	VISIT 6	2016-06-20		
	ND plus	ES/SAF/FAS	VISIT 7	2016-12-14		
	ND plus	ES/SAF/FAS	VISIT 8	2017-12-13		
	ND plus	ES/SAF/FAS	VISIT 9	2018-12-12		
	ND plus	ES/SAF/FAS	VISIT 10	2019-12-28		
	ND plus	ES/SAF/FAS	VISIT 11	2021-02-08		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2019-02-13		
01/0149	ND plus	ES/SAF/FAS	VISIT 1	2015-12-01		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Page 17 of 45

-continued on next page-

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
01/0149	ND plus	ES/SAF/FAS	VISIT 2A	2015-12-02		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-12-03		
	ND plus	ES/SAF/FAS	VISIT 3A	2016-03-01		
	ND plus	ES/SAF/FAS	VISIT 3B	2016-03-01		
	ND plus	ES/SAF/FAS	VISIT 4	2016-04-13		
	ND plus	ES/SAF/FAS	VISIT 5	2016-06-01		
	ND plus	ES/SAF/FAS	VISIT 6	2016-09-14		
	ND plus	ES/SAF/FAS	VISIT 7	2017-03-15		
	ND plus	ES/SAF/FAS	VISIT 8	2018-03-14		
	ND plus	ES/SAF/FAS	VISIT 9	2019-03-12		
	ND plus	ES/SAF/FAS	VISIT 10	2020-02-12		
	ND plus	ES/SAF/FAS	VISIT 11	2021-02-24		
	ND plus	ES/SAF/FAS	END OF TRIAL			
01/0150		ES	VISIT 1	2016-02-02		
		ES	VISIT 2A	2016-02-02		
		ES	VISIT 2B	2016-02-03		
		ES	END OF TRIAL		2016-02-03	Other reason
01/0151	ND basic	ES/SAF/FAS	VISIT 1	2016-03-01		
	ND basic	ES/SAF/FAS	VISIT 2A	2016-03-01		
	ND basic	ES/SAF/FAS	VISIT 2B	2016-03-03		
	ND basic	ES/SAF/FAS	VISIT 3A	2016-06-07		
	ND basic	ES/SAF/FAS	VISIT 3B	2016-06-07		
	ND basic	ES/SAF/FAS	VISIT 4	2016-07-13		
	ND basic	ES/SAF/FAS	VISIT 5	2016-09-07		
	ND basic	ES/SAF/FAS	VISIT 6	2016-11-30		
	ND basic	ES/SAF/FAS	VISIT 7	2017-05-31		
	ND basic	ES/SAF/FAS	VISIT 8	2018-05-02		
	ND basic	ES/SAF/FAS	VISIT 9	2019-05-13		
	ND basic	ES/SAF/FAS	VISIT 10	2020-05-11		
	ND basic	ES/SAF/FAS	VISIT 11	2021-05-12		
	ND basic	ES/SAF/FAS	END OF TRIAL			
01/0152	SC	ES/SAF/FAS	VISIT 1	2016-03-02		
	SC	ES/SAF/FAS	VISIT 2A	2016-03-02		
	SC	ES/SAF/FAS	VISIT 2B	2016-03-03		
	SC	ES/SAF/FAS	VISIT 4	2016-04-21		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
01/0152	SC	ES/SAF/FAS	VISIT 5	2016-05-25		
	SC	ES/SAF/FAS	VISIT 6	2016-08-24		
	SC	ES/SAF/FAS	VISIT 7	2017-02-22		
	SC	ES/SAF/FAS	VISIT 8	2018-03-07		
	SC	ES/SAF/FAS	VISIT 9	2019-03-11		
	SC	ES/SAF/FAS	VISIT 10	2020-02-10		
	SC	ES/SAF/FAS	VISIT 11	2021-03-10		
	SC	ES/SAF/FAS	END OF TRIAL			
01/0153	ND basic	ES/SAF/FAS	VISIT 1	2016-03-18		
	ND basic	ES/SAF/FAS	VISIT 2A	2016-03-20		
	ND basic	ES/SAF/FAS	VISIT 2B	2016-03-21		
	ND basic	ES/SAF/FAS	VISIT 3A	2016-06-07		
	ND basic	ES/SAF/FAS	VISIT 3B	2016-06-07		
	ND basic	ES/SAF/FAS	VISIT 4	2016-07-20		
	ND basic	ES/SAF/FAS	VISIT 5	2016-09-07		
	ND basic	ES/SAF/FAS	VISIT 6	2016-11-30		
	ND basic	ES/SAF/FAS	VISIT 7	2017-05-31		
	ND basic	ES/SAF/FAS	VISIT 8	2018-05-02		
	ND basic	ES/SAF/FAS	VISIT 9	2019-05-09		
	ND basic	ES/SAF/FAS	VISIT 10	2020-05-13		
	ND basic	ES/SAF/FAS	VISIT 11	2021-06-14		
	ND basic	ES/SAF/FAS	END OF TRIAL			
	ND basic	ES/SAF/FAS	UNSCHEDULED	2016-06-22		
	ND basic	ES/SAF/FAS	UNSCHEDULED	2017-07-26		
	ND basic	ES/SAF/FAS	UNSCHEDULED	2018-11-19		
02/0201	ND plus	ES/SAF/FAS	VISIT 1	2013-02-12		
	ND plus	ES/SAF/FAS	VISIT 2A	2013-02-13		
	ND plus	ES/SAF/FAS	VISIT 2B	2013-02-13		
	ND plus	ES/SAF/FAS	VISIT 3A	2013-05-07		
	ND plus	ES/SAF/FAS	VISIT 3B	2013-05-07		
	ND plus	ES/SAF/FAS	VISIT 3K	2013-05-09		
	ND plus	ES/SAF/FAS	VISIT 3L	2013-05-28		
	ND plus	ES/SAF/FAS	VISIT 4	2013-06-20		
	ND plus	ES/SAF/FAS	VISIT 5	2013-07-31		
	ND plus	ES/SAF/FAS	VISIT 6	2013-10-29		
	ND plus	ES/SAF/FAS	VISIT 7	2014-05-06		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
02/0201	ND plus	ES/SAF/FAS	VISIT 8	2015-06-02		
	ND plus	ES/SAF/FAS	VISIT 9	2016-04-29		
	ND plus	ES/SAF/FAS	VISIT 10	2017-04-24		
	ND plus	ES/SAF/FAS	VISIT 11	2018-05-29		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2015-12-28		
02/0202	ND basic	ES/SAF	VISIT 1	2013-03-19		
	ND basic	ES/SAF	VISIT 2A	2013-03-19		
	ND basic	ES/SAF	VISIT 2B	2013-03-20		
	ND basic	ES/SAF	END OF TRIAL		2013-09-09	Withdrawal of clinical trial subject's consent
02/0203	ND basic	ES/SAF/FAS	VISIT 1	2013-03-27		
	ND basic	ES/SAF/FAS	VISIT 2A	2013-03-28		
	ND basic	ES/SAF/FAS	VISIT 2B	2013-03-28		
	ND basic	ES/SAF/FAS	VISIT 3A	2013-06-25		
	ND basic	ES/SAF/FAS	VISIT 3B	2013-06-26		
	ND basic	ES/SAF/FAS	VISIT 3K	2013-06-28		
	ND basic	ES/SAF/FAS	VISIT 3L	2013-07-24		
	ND basic	ES/SAF/FAS	VISIT 4	2013-08-13		
	ND basic	ES/SAF/FAS	VISIT 5	2013-09-24		
	ND basic	ES/SAF/FAS	VISIT 6	2013-12-10		
	ND basic	ES/SAF/FAS	VISIT 7	2014-06-26		
	ND basic	ES/SAF/FAS	VISIT 8	2015-06-24		
	ND basic	ES/SAF/FAS	VISIT 9	2016-06-09		
	ND basic	ES/SAF/FAS	VISIT 10	2017-06-05		
	ND basic	ES/SAF/FAS	VISIT 11	2018-06-26		
	ND basic	ES/SAF/FAS	END OF TRIAL			
	ND basic	ES/SAF/FAS	UNSCHEDULED	2014-02-26		
	ND basic	ES/SAF/FAS	UNSCHEDULED	2014-03-05		
	ND basic	ES/SAF/FAS	UNSCHEDULED	2016-02-10		
	ND basic	ES/SAF/FAS	UNSCHEDULED	2016-07-20		
	ND basic	ES/SAF/FAS	UNSCHEDULED	2016-08-11		
02/0204	ND basic	ES/SAF	VISIT 1	2013-04-17		
	ND basic	ES/SAF	VISIT 2A	2013-04-17		
	ND basic	ES/SAF	VISIT 2B	2013-04-18		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
02/0204	ND basic	ES/SAF	END OF TRIAL		2013-07-10	Other reason
02/0205	ND basic	ES/SAF/FAS	VISIT 1	2013-04-17		
	ND basic	ES/SAF/FAS	VISIT 2A	2013-04-17		
	ND basic	ES/SAF/FAS	VISIT 2B	2013-04-18		
	ND basic	ES/SAF/FAS	VISIT 3A	2013-07-30		
	ND basic	ES/SAF/FAS	VISIT 3B	2013-07-31		
	ND basic	ES/SAF/FAS	VISIT 3K	2013-08-02		
	ND basic	ES/SAF/FAS	VISIT 3L	2013-08-21		
	ND basic	ES/SAF/FAS	VISIT 4	2013-09-17		
	ND basic	ES/SAF/FAS	VISIT 5	2013-10-28		
	ND basic	ES/SAF/FAS	VISIT 6	2014-01-23		
	ND basic	ES/SAF/FAS	VISIT 7	2014-08-12		
	ND basic	ES/SAF/FAS	VISIT 8	2015-08-21		
	ND basic	ES/SAF/FAS	VISIT 9	2016-08-03		
	ND basic	ES/SAF/FAS	VISIT 10	2017-06-15		
	ND basic	ES/SAF/FAS	VISIT 11	2018-08-28		
	ND basic	ES/SAF/FAS	END OF TRIAL			
02/0206	ND plus	ES/SAF/FAS	VISIT 1	2013-06-27		
	ND plus	ES/SAF/FAS	VISIT 2A	2013-06-27		
	ND plus	ES/SAF/FAS	VISIT 2B	2013-07-01		
	ND plus	ES/SAF/FAS	VISIT 3A	2013-10-07		
	ND plus	ES/SAF/FAS	VISIT 3B	2013-10-08		
	ND plus	ES/SAF/FAS	VISIT 3K	2013-10-11		
	ND plus	ES/SAF/FAS	VISIT 3L	2013-10-29		
	ND plus	ES/SAF/FAS	VISIT 4	2013-11-20		
	ND plus	ES/SAF/FAS	VISIT 5	2014-01-03		
	ND plus	ES/SAF/FAS	VISIT 6	2014-03-07		
	ND plus	ES/SAF/FAS	VISIT 7	2014-07-11		
	ND plus	ES/SAF/FAS	VISIT 9	2016-10-04		
	ND plus	ES/SAF/FAS	VISIT 10	2017-08		
	ND plus	ES/SAF/FAS	VISIT 11	2018-08-30		
	ND plus	ES/SAF/FAS	END OF TRIAL			
02/0207		ES	VISIT 1	2013-07-23		
		ES	VISIT 2A	2013-07-23		
		ES	VISIT 2B	2013-07-24		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Page 21 of 45

-continued on next page-

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
02/0207		ES	END OF TRIAL		2013-07-24	Inclusion/Exclusion criteria not met Excl. crit. intra-surgery.Extensive damage of annulus intra-operative
02/0208	ND plus	ES/SAF/FAS	VISIT 1	2013-09-11		
	ND plus	ES/SAF/FAS	VISIT 2A	2013-09-11		
	ND plus	ES/SAF/FAS	VISIT 2B	2013-09-12		
	ND plus	ES/SAF/FAS	VISIT 3A	2013-12-09		
	ND plus	ES/SAF/FAS	VISIT 3B	2013-12-10		
	ND plus	ES/SAF/FAS	VISIT 3K	2013-12-12		
	ND plus	ES/SAF/FAS	VISIT 3L	2013-12-30		
	ND plus	ES/SAF/FAS	VISIT 4	2014-01-22		
	ND plus	ES/SAF/FAS	VISIT 5	2014-03-25		
	ND plus	ES/SAF/FAS	VISIT 6	2014-05-28		
	ND plus	ES/SAF/FAS	VISIT 7	2014-12-30		
	ND plus	ES/SAF/FAS	VISIT 8	2015-12-17		
	ND plus	ES/SAF/FAS	VISIT 9	2016-12-19		
	ND plus	ES/SAF/FAS	VISIT 10	2017-11-27		
	ND plus	ES/SAF/FAS	VISIT 11	2018-12-27		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2013-12-16		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2014-04-01		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2015-09-01		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2015-09-21		
02/0209	ND plus	ES/SAF/FAS	VISIT 1	2014-10-22		
	ND plus	ES/SAF/FAS	VISIT 2B	2014-10-23		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-01-29		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-01-30		
	ND plus	ES/SAF/FAS	VISIT 4	2015-03-24		
	ND plus	ES/SAF/FAS	VISIT 5	2015-04-29		
	ND plus	ES/SAF/FAS	VISIT 6	2015-07-16		
	ND plus	ES/SAF/FAS	VISIT 7	2016-02-23		
	ND plus	ES/SAF/FAS	VISIT 8	2017-01-19		
	ND plus	ES/SAF/FAS	VISIT 9	2018-01-08		
	ND plus	ES/SAF/FAS	VISIT 10	2019-01-09		
	ND plus	ES/SAF/FAS	VISIT 11	2019-12-30		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
02/0209	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2015-11-05		
02/0210		ES	VISIT 1	2014-11-12		
		ES	VISIT 2A	2014-11-12		
		ES	VISIT 2B	2014-11-13		
		ES	END OF TRIAL		2014-11-13	Inclusion/Exclusion criteria not met Exclusion intra-surgery
02/0211	ND basic	ES/SAF	VISIT 1	2014-12-10		
	ND basic	ES/SAF	VISIT 2A	2014-12-10		
	ND basic	ES/SAF	VISIT 2B	2014-12-11		
	ND basic	ES/SAF	VISIT 3A	2015-03-04		
	ND basic	ES/SAF	END OF TRIAL		2015-03-04	Inclusion/Exclusion criteria not met Reextrusion and defect anulus
02/0212	SC	ES/SAF/FAS	VISIT 1	2014-12-15		
	SC	ES/SAF/FAS	VISIT 2A	2014-12-15		
	SC	ES/SAF/FAS	VISIT 2B	2014-12-16		
	SC	ES/SAF/FAS	VISIT 4	2015-01-30		
	SC	ES/SAF/FAS	VISIT 5	2015-04-10		
	SC	ES/SAF/FAS	VISIT 6	2015-06-25		
	SC	ES/SAF/FAS	VISIT 7	2016-01-28		
	SC	ES/SAF/FAS	VISIT 8	2016-12-28		
	SC	ES/SAF/FAS	VISIT 9	2017-11-15		
	SC	ES/SAF/FAS	VISIT 10	2019-04-16		
	SC	ES/SAF/FAS	VISIT 11	2019-12-27		
	SC	ES/SAF/FAS	END OF TRIAL			
02/0213	ND plus	ES/SAF	VISIT 1	2014-12-17		
	ND plus	ES/SAF	VISIT 2A	2014-12-17		
	ND plus	ES/SAF	VISIT 2B	2014-12-18		
	ND plus	ES/SAF	END OF TRIAL		2015-03-09	Withdrawal of clinical trial subject's consent
02/0214	ND plus	ES/SAF/FAS	VISIT 1	2015-02-24		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-02-24		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-02-25		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-05-27		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
02/0214	ND plus	ES/SAF/FAS	VISIT 3B	2015-05-28		
	ND plus	ES/SAF/FAS	VISIT 4	2015-07-23		
	ND plus	ES/SAF/FAS	VISIT 6	2015-12-03		
	ND plus	ES/SAF/FAS	VISIT 7	2016-05-26		
	ND plus	ES/SAF/FAS	VISIT 9	2018-05-22		
	ND plus	ES/SAF/FAS	VISIT 11	2020-10-15		
	ND plus	ES/SAF/FAS	END OF TRIAL			
02/0215		ES	VISIT 1	2015-03-04		
		ES	VISIT 2A	2015-03-04		
		ES	VISIT 2B	2015-03-05		
		ES	END OF TRIAL		2015-03-05	Inclusion/Exclusion criteria not met
						intraoperative Inclusion Criteria not met
02/0216	ND plus	ES/SAF/FAS	VISIT 1	2015-04-27		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-04-27		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-04-28		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-07-22		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-07-23		
	ND plus	ES/SAF/FAS	VISIT 4	2015-08-21		
	ND plus	ES/SAF/FAS	VISIT 5	2015-10-21		
	ND plus	ES/SAF/FAS	END OF TRIAL		2016-03-29	Loss of interest for participation
	ND plus	ES/SAF/FAS	UNSCHEDULED	2015-07-29		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2015-08-07		
02/0217	SC	ES/SAF/FAS	VISIT 1	2015-05-27		
	SC	ES/SAF/FAS	VISIT 2B	2015-05-28		
	SC	ES/SAF/FAS	VISIT 4	2015-07-14		
	SC	ES/SAF/FAS	VISIT 5	2015-08-30		
	SC	ES/SAF/FAS	VISIT 6	2015-12-08		
	SC	ES/SAF/FAS	VISIT 7	2016-05-11		
	SC	ES/SAF/FAS	VISIT 8	2017-04-27		
	SC	ES/SAF/FAS	VISIT 9	2018-05-02		
	SC	ES/SAF/FAS	VISIT 10	2019-05-02		
	SC	ES/SAF/FAS	VISIT 11	2020-07-01		
	SC	ES/SAF/FAS	END OF TRIAL			
02/0218	ND basic	ES/SAF	VISIT 1	2015-06-16		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
02/0218	ND basic	ES/SAF	VISIT 2A	2015-06-29	2015-08-04	Withdrawal of clinical trial subject's consent
	ND basic	ES/SAF	VISIT 2B	2015-06-30		
	ND basic	ES/SAF	END OF TRIAL			
02/0219	ND basic	ES/SAF/FAS	VISIT 1	2015-06-10		
	ND basic	ES/SAF/FAS	VISIT 2A	2015-06-10		
	ND basic	ES/SAF/FAS	VISIT 2B	2015-06-11		
	ND basic	ES/SAF/FAS	VISIT 3A	2015-09-24		
	ND basic	ES/SAF/FAS	VISIT 3B	2015-09-25		
	ND basic	ES/SAF/FAS	VISIT 4	2015-11-04		
	ND basic	ES/SAF/FAS	VISIT 5	2015-12-17		
	ND basic	ES/SAF/FAS	VISIT 6	2016-04-04		
	ND basic	ES/SAF/FAS	VISIT 7	2016-08-22		
	ND basic	ES/SAF/FAS	VISIT 8	2017-09-20		
	ND basic	ES/SAF/FAS	VISIT 9	2018-11-29		
	ND basic	ES/SAF/FAS	VISIT 10	2019-09-19		
	ND basic	ES/SAF/FAS	VISIT 11	2020-08-26		
	ND basic	ES/SAF/FAS	END OF TRIAL			
02/0220	SC	ES/SAF/FAS	VISIT 1	2015-08-12		
	SC	ES/SAF/FAS	VISIT 2A	2015-08-12		
	SC	ES/SAF/FAS	VISIT 2B	2015-08-13		
	SC	ES/SAF/FAS	VISIT 4	2015-09-29		
	SC	ES/SAF/FAS	VISIT 5	2015-11-17		
	SC	ES/SAF/FAS	VISIT 6	2016-01-26		
	SC	ES/SAF/FAS	VISIT 7	2016-08-04		
	SC	ES/SAF/FAS	VISIT 8	2017-07-19		
	SC	ES/SAF/FAS	VISIT 9	2018-08-14		
	SC	ES/SAF/FAS	VISIT 10	2019-07-19		
	SC	ES/SAF/FAS	VISIT 11	2020-09-02		
	SC	ES/SAF/FAS	END OF TRIAL			
02/0221	ND plus	ES/SAF	VISIT 1	2015-08-31	2015-12-10	Inclusion/Exclusion criteria not met
	ND plus	ES/SAF	VISIT 2A	2015-08-31		
	ND plus	ES/SAF	VISIT 2B	2015-09-01		
	ND plus	ES/SAF	VISIT 3A	2015-12-10		
	ND plus	ES/SAF	END OF TRIAL			

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
02/0222	ND plus	ES/SAF	VISIT 1	2015-09-09	2015-12-15	Withdrawal of clinical trial subject's consent
	ND plus	ES/SAF	VISIT 2A	2015-09-09		
	ND plus	ES/SAF	VISIT 2B	2015-09-10		
	ND plus	ES/SAF	END OF TRIAL			
02/0223	ND basic	ES/SAF/FAS	VISIT 1	2015-12-28	2016-03-08	Withdrawal of clinical trial subject's consent
	ND basic	ES/SAF/FAS	VISIT 2A	2015-12-28		
	ND basic	ES/SAF/FAS	VISIT 2B	2015-12-29		
	ND basic	ES/SAF/FAS	VISIT 3A	2016-03-21		
	ND basic	ES/SAF/FAS	VISIT 3B	2016-03-22		
	ND basic	ES/SAF/FAS	VISIT 4	2016-04-27		
	ND basic	ES/SAF/FAS	VISIT 5	2016-07-05		
	ND basic	ES/SAF/FAS	VISIT 6	2016-08-24		
	ND basic	ES/SAF/FAS	VISIT 7	2017-03-15		
	ND basic	ES/SAF/FAS	VISIT 8	2018-03-07		
	ND basic	ES/SAF/FAS	VISIT 9	2019-02-21		
	ND basic	ES/SAF/FAS	VISIT 10	2020-02-26		
	ND basic	ES/SAF/FAS	VISIT 11	2021-03-03		
	ND basic	ES/SAF/FAS	END OF TRIAL			
02/0224	ND plus	ES/SAF	VISIT 1	2015-12-28	2016-03-08	Withdrawal of clinical trial subject's consent
	ND plus	ES/SAF	VISIT 2A	2015-12-28		
	ND plus	ES/SAF	VISIT 2B	2015-12-29		
	ND plus	ES/SAF	END OF TRIAL			
04/0401	SC	ES/SAF/FAS	VISIT 1	2015-06-24		
	SC	ES/SAF/FAS	VISIT 2A	2015-06-24		
	SC	ES/SAF/FAS	VISIT 2B	2015-06-30		
	SC	ES/SAF/FAS	VISIT 4	2015-08-11		
	SC	ES/SAF/FAS	VISIT 5	2015-10-08		
	SC	ES/SAF/FAS	VISIT 6	2015-12-16		
	SC	ES/SAF/FAS	VISIT 7	2016-06-21		
	SC	ES/SAF/FAS	VISIT 8	2017-07-05		
	SC	ES/SAF/FAS	VISIT 9	2018-07-25		
	SC	ES/SAF/FAS	VISIT 10	2019-07-11		
	SC	ES/SAF/FAS	VISIT 11	2020-07-27		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
04/0401	SC	ES/SAF/FAS	END OF TRIAL			
06/0601		ES	VISIT 1	2013-04-22	2013-04-22	Other reason
06/0602	ND plus	ES/SAF/FAS	VISIT 1	2013-07-22		
	ND plus	ES/SAF/FAS	VISIT 2A	2013-07-22		
	ND plus	ES/SAF/FAS	VISIT 2B	2013-07-23		
	ND plus	ES/SAF/FAS	VISIT 3A	2013-11-04		
	ND plus	ES/SAF/FAS	VISIT 3B	2013-11-05		
	ND plus	ES/SAF/FAS	VISIT 3K	2013-11-07		
	ND plus	ES/SAF/FAS	VISIT 4	2013-12-18		
	ND plus	ES/SAF/FAS	VISIT 5	2014-02-12		
	ND plus	ES/SAF/FAS	VISIT 6	2014-04-22		
	ND plus	ES/SAF/FAS	VISIT 7	2014-10-23		
	ND plus	ES/SAF/FAS	VISIT 8	2015-11-18		
	ND plus	ES/SAF/FAS	END OF TRIAL		2019-01-28	Lack of compliance
06/0604	ND basic	ES/SAF	VISIT 1	2014-10-27		
	ND basic	ES/SAF	VISIT 2A	2014-10-27		
	ND basic	ES/SAF	VISIT 2B	2014-10-28		
	ND basic	ES/SAF	END OF TRIAL		2015-02-04	Other reason
06/0605	ND plus	ES/SAF	VISIT 1	2014-12-10		
	ND plus	ES/SAF	VISIT 2A	2014-12-11		
	ND plus	ES/SAF	VISIT 2B	2014-12-11		
	ND plus	ES/SAF	END OF TRIAL		2015-02-13	Other reason
06/0606	SC	ES/SAF/FAS	VISIT 1	2014-12-15		
	SC	ES/SAF/FAS	VISIT 2A	2014-12-15		
	SC	ES/SAF/FAS	VISIT 2B	2014-12-16		
	SC	ES/SAF/FAS	VISIT 4	2015-02-10		
	SC	ES/SAF/FAS	VISIT 5	2015-03-12		
	SC	ES/SAF/FAS	VISIT 6	2015-06-03		
	SC	ES/SAF/FAS	VISIT 7	2015-12-03		
	SC	ES/SAF/FAS	VISIT 8	2016-11-24		
	SC	ES/SAF/FAS	VISIT 9	2018-01-12		
	SC	ES/SAF/FAS	VISIT 10	2019-01-31		
	SC	ES/SAF/FAS	VISIT 11	2019-12-03		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
06/0606	SC	ES/SAF/FAS	END OF TRIAL			
06/0607	ND plus	ES/SAF/FAS	VISIT 1	2015-01-19		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-01-19		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-01-20		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-04-14		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-04-15		
	ND plus	ES/SAF/FAS	VISIT 4	2015-06-01		
	ND plus	ES/SAF/FAS	VISIT 5	2015-07-21		
	ND plus	ES/SAF/FAS	VISIT 6	2015-10-06		
	ND plus	ES/SAF/FAS	VISIT 7	2016-04-05		
	ND plus	ES/SAF/FAS	VISIT 8	2017-04-05		
	ND plus	ES/SAF/FAS	VISIT 9	2018-03-25		
	ND plus	ES/SAF/FAS	VISIT 10	2019-04-01		
	ND plus	ES/SAF/FAS	VISIT 11	2020-03-16		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2018-03-28		
06/0608	SC	ES/SAF	VISIT 1	2015-01-27		
	SC	ES/SAF	VISIT 2A	2015-01-27		
	SC	ES/SAF	VISIT 2B	2015-01-29		
	SC	ES/SAF	END OF TRIAL		2015-02-19	Inclusion/Exclusion criteria not met active hepatitis B
06/0609	ND basic	ES/SAF	VISIT 1	2015-04-15		
	ND basic	ES/SAF	VISIT 2A	2015-04-15		
	ND basic	ES/SAF	VISIT 2B	2015-04-16		
	ND basic	ES/SAF	END OF TRIAL		2015-07-06	Other reason
06/0610	ND plus	ES/SAF/FAS	VISIT 1	2015-06-24		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-06-24		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-06-25		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-09-07		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-09-08		
	ND plus	ES/SAF/FAS	VISIT 4	2015-10-26		
	ND plus	ES/SAF/FAS	VISIT 5	2015-12-14		
	ND plus	ES/SAF/FAS	VISIT 6	2016-03-16		
	ND plus	ES/SAF/FAS	VISIT 7	2016-08-30		
	ND plus	ES/SAF/FAS	VISIT 8	2017-10-10		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
06/0610	ND plus	ES/SAF/FAS	VISIT 11	2020-09-07		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2016-01-19		
06/0611		ES	VISIT 1	2015-07-14		
		ES	VISIT 2A	2015-07-14		
		ES	VISIT 2B	2015-07-15		
		ES	END OF TRIAL		2015-07-15	Inclusion/Exclusion criteria not met Anulus Defect > 8 mm
06/0612	ND plus	ES/SAF/FAS	VISIT 1	2015-07-14		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-07-14		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-07-15		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-10-19		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-10-20		
	ND plus	ES/SAF/FAS	VISIT 4	2015-11-25		
	ND plus	ES/SAF/FAS	VISIT 5	2016-01-11		
	ND plus	ES/SAF/FAS	VISIT 6	2016-04-11		
	ND plus	ES/SAF/FAS	VISIT 7	2016-10-26		
	ND plus	ES/SAF/FAS	VISIT 8	2017-10-19		
	ND plus	ES/SAF/FAS	VISIT 9	2018-10-24		
	ND plus	ES/SAF/FAS	VISIT 10	2019-10-30		
	ND plus	ES/SAF/FAS	VISIT 11	2020-10-14		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2016-05-19		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2019-11-28		
06/0613	SC	ES/SAF/FAS	VISIT 1	2015-07-17		
	SC	ES/SAF/FAS	VISIT 2A	2015-07-17		
	SC	ES/SAF/FAS	VISIT 2B	2015-07-20		
	SC	ES/SAF/FAS	VISIT 4	2015-09-04		
	SC	ES/SAF/FAS	VISIT 5	2015-10-16		
	SC	ES/SAF/FAS	VISIT 6	2016-01-15		
	SC	ES/SAF/FAS	VISIT 7	2016-07-15		
	SC	ES/SAF/FAS	VISIT 8	2017-08-09		
	SC	ES/SAF/FAS	VISIT 9	2018-08-09		
	SC	ES/SAF/FAS	VISIT 10	2019-08-05		
	SC	ES/SAF/FAS	VISIT 11	2020-08-11		
	SC	ES/SAF/FAS	END OF TRIAL			

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
06/0614	ND plus	ES/SAF/FAS	VISIT 1	2015-08-14		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-08-14		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-08-18		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-11-16		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-11-18		
	ND plus	ES/SAF/FAS	VISIT 4	2016-01-04		
	ND plus	ES/SAF/FAS	VISIT 5	2016-02-09		
	ND plus	ES/SAF/FAS	VISIT 6	2016-05-02		
	ND plus	ES/SAF/FAS	VISIT 7	2016-11-17		
	ND plus	ES/SAF/FAS	VISIT 8	2017-11-02		
	ND plus	ES/SAF/FAS	VISIT 9	2018-12-18		
	ND plus	ES/SAF/FAS	VISIT 10	2019-11-18		
	ND plus	ES/SAF/FAS	VISIT 11	2020-12-10		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2016-02-22		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2016-03-10		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2016-08-03		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2016-08-10		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2017-11-15		
06/0615	ND basic	ES/SAF	VISIT 1	2015-08-21		
	ND basic	ES/SAF	VISIT 2A	2015-08-21		
	ND basic	ES/SAF	VISIT 2B	2015-08-25		
	ND basic	ES/SAF	END OF TRIAL		2015-11-16	Withdrawal of clinical trial subject's consent
06/0616		ES	VISIT 1	2015-11-05		
		ES	VISIT 2A	2015-11-05		
		ES	VISIT 2B	2015-11-09		
		ES	END OF TRIAL		2015-11-09	Inclusion/Exclusion criteria not met ANULUS DEFECT
06/0617	ND plus	ES/SAF	VISIT 1	2015-12-21		
	ND plus	ES/SAF	VISIT 2A	2015-12-21		
	ND plus	ES/SAF	VISIT 2B	2015-12-22		
	ND plus	ES/SAF	VISIT 3A	2016-03-08		
	ND plus	ES/SAF	END OF TRIAL		2016-03-08	Inclusion/Exclusion criteria not met recurrence of lumbar disc L4 L5

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
06/0618		ES	VISIT 1	2016-01-14		
		ES	VISIT 2A	2016-01-14		
		ES	VISIT 2B	2016-01-18		
		ES	END OF TRIAL		2016-01-18	Inclusion/Exclusion criteria not met intra operative exclusion Anulus defect
06/0619	ND basic	ES/SAF/FAS	VISIT 1	2016-02-22		
	ND basic	ES/SAF/FAS	VISIT 2A	2016-02-22		
	ND basic	ES/SAF/FAS	VISIT 2B	2016-02-23		
	ND basic	ES/SAF/FAS	VISIT 3A	2016-05-09		
	ND basic	ES/SAF/FAS	VISIT 3B	2016-05-10		
	ND basic	ES/SAF/FAS	VISIT 4	2016-06-20		
	ND basic	ES/SAF/FAS	VISIT 5	2016-08-04		
	ND basic	ES/SAF/FAS	VISIT 6	2016-11-03		
	ND basic	ES/SAF/FAS	VISIT 7	2017-05-15		
	ND basic	ES/SAF/FAS	VISIT 8	2018-05-02		
	ND basic	ES/SAF/FAS	VISIT 9	2019-05-19		
	ND basic	ES/SAF/FAS	VISIT 10	2020-04-15		
	ND basic	ES/SAF/FAS	VISIT 11	2021-05-28		
	ND basic	ES/SAF/FAS	END OF TRIAL			
06/0620	SC	ES/SAF/FAS	VISIT 1	2016-02-23		
	SC	ES/SAF/FAS	VISIT 2A	2016-02-23		
	SC	ES/SAF/FAS	VISIT 2B	2016-02-24		
	SC	ES/SAF/FAS	VISIT 4	2016-04-12		
	SC	ES/SAF/FAS	VISIT 5	2016-05-23		
	SC	ES/SAF/FAS	VISIT 6	2016-08-17		
	SC	ES/SAF/FAS	VISIT 7	2017-02-20		
	SC	ES/SAF/FAS	VISIT 8	2018-03-26		
	SC	ES/SAF/FAS	VISIT 9	2019-03-07		
	SC	ES/SAF/FAS	VISIT 10	2020-02-29		
	SC	ES/SAF/FAS	VISIT 11	2021-03-02		
	SC	ES/SAF/FAS	END OF TRIAL			
	SC	ES/SAF/FAS	END OF TRIAL			
07/0701	ND plus	ES/SAF/FAS	VISIT 1	2014-11-04		
	ND plus	ES/SAF/FAS	VISIT 2A	2014-11-05		
	ND plus	ES/SAF/FAS	VISIT 2B	2014-11-06		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-01-19		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
07/0701	ND plus	ES/SAF/FAS	VISIT 3B	2015-01-20		
	ND plus	ES/SAF/FAS	VISIT 4	2015-03-04		
	ND plus	ES/SAF/FAS	VISIT 5	2015-04-27		
	ND plus	ES/SAF/FAS	VISIT 6	2015-07-20		
	ND plus	ES/SAF/FAS	VISIT 7	2016-01-14		
	ND plus	ES/SAF/FAS	VISIT 8	2017-01-30		
	ND plus	ES/SAF/FAS	VISIT 9	2018-01-15		
	ND plus	ES/SAF/FAS	VISIT 10	2019-02-05		
	ND plus	ES/SAF/FAS	VISIT 11	2020-02-12		
07/0702	ND plus	ES/SAF/FAS	END OF TRIAL			
	SC	ES/SAF/FAS	VISIT 1	2015-01-19		
	SC	ES/SAF/FAS	VISIT 2A	2015-01-19		
	SC	ES/SAF/FAS	VISIT 2B	2015-01-20		
	SC	ES/SAF/FAS	VISIT 4	2015-03-02		
	SC	ES/SAF/FAS	VISIT 5	2015-04-20		
	SC	ES/SAF/FAS	VISIT 6	2015-07-21		
	SC	ES/SAF/FAS	VISIT 8	2018-02-14		
	SC	ES/SAF/FAS	VISIT 10	2019-02-18		
07/0703	SC	ES/SAF/FAS	VISIT 11	ND		
	SC	ES/SAF/FAS	END OF TRIAL		2020-02-20	Other reason
	ND plus	ES/SAF/FAS	VISIT 1	2015-02-27		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-03-02		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-03-03		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-05-18		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-05-19		
	ND plus	ES/SAF/FAS	VISIT 4	2015-06-29		
	ND plus	ES/SAF/FAS	VISIT 5	2015-08-17		
07/0704	ND plus	ES/SAF/FAS	VISIT 6	2015-11-09		
	ND plus	ES/SAF/FAS	VISIT 7	2016-05-09		
	ND plus	ES/SAF/FAS	VISIT 8	2017-04-24		
	ND plus	ES/SAF/FAS	VISIT 9	2018-06-15		
	ND plus	ES/SAF/FAS	VISIT 10	2019-04-23		
	ND plus	ES/SAF/FAS	VISIT 11	2020-07-20		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND basic	ES/SAF/FAS	VISIT 1	2015-07-14		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
07/0704	ND basic	ES/SAF/FAS	VISIT 2A	2015-07-15		
	ND basic	ES/SAF/FAS	VISIT 2B	2015-07-16		
	ND basic	ES/SAF/FAS	VISIT 3A	2015-10-06		
	ND basic	ES/SAF/FAS	VISIT 3B	2015-10-08		
	ND basic	ES/SAF/FAS	VISIT 4	2015-11-16		
	ND basic	ES/SAF/FAS	VISIT 5	2016-01-11		
	ND basic	ES/SAF/FAS	VISIT 6	2016-04-11		
	ND basic	ES/SAF/FAS	VISIT 7	2016-11-21		
	ND basic	ES/SAF/FAS	VISIT 8	2017-10-02		
	ND basic	ES/SAF/FAS	VISIT 9	2018-10-08		
	ND basic	ES/SAF/FAS	VISIT 10	2019-09-10		
	ND basic	ES/SAF/FAS	VISIT 11	2020-09-21		
	ND basic	ES/SAF/FAS	END OF TRIAL			
07/0705		ES	VISIT 1	2015-08-11		
		ES	VISIT 2A	2015-08-12		
		ES	VISIT 2B	2015-08-13		
		ES	END OF TRIAL		2015-08-13	Inclusion/Exclusion criteria not met Due to intraop anulus defect
07/0706	SC	ES/SAF/FAS	VISIT 1	2015-11-30		
	SC	ES/SAF/FAS	VISIT 2A	2015-11-30		
	SC	ES/SAF/FAS	VISIT 2B	2015-12-01		
	SC	ES/SAF/FAS	VISIT 4	2016-01-12		
	SC	ES/SAF/FAS	END OF TRIAL		2016-02-28	Withdrawal of clinical trial subject's consent
07/0707		ES	VISIT 1	2016-02-18		
		ES	VISIT 2A	2016-02-20		
		ES	END OF TRIAL		2016-02-22	Withdrawal of clinical trial subject's consent
08/0801	SC	ES/SAF/FAS	VISIT 1	2014-10-31		
	SC	ES/SAF/FAS	VISIT 2A	2014-11-02		
	SC	ES/SAF/FAS	VISIT 2B	2014-11-03		
	SC	ES/SAF/FAS	VISIT 4	2014-12-22		
	SC	ES/SAF/FAS	VISIT 5	2015-02-12		
	SC	ES/SAF/FAS	VISIT 6	2015-05-04		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
08/0801	SC	ES/SAF/FAS	END OF TRIAL		2015-11-17	Lack of compliance
08/0802	ND plus	ES/SAF/FAS	VISIT 1	2014-11-26		
	ND plus	ES/SAF/FAS	VISIT 2A	2014-11-26		
	ND plus	ES/SAF/FAS	VISIT 2B	2014-11-27		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-03-03		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-03-04		
	ND plus	ES/SAF/FAS	VISIT 4	2015-04-08		
	ND plus	ES/SAF/FAS	VISIT 5	2015-06-01		
	ND plus	ES/SAF/FAS	VISIT 6	2015-08-17		
	ND plus	ES/SAF/FAS	VISIT 7	2016-02-22		
	ND plus	ES/SAF/FAS	VISIT 8	2017-02-02		
	ND plus	ES/SAF/FAS	VISIT 9	2018-04-01		
	ND plus	ES/SAF/FAS	VISIT 10	2019-03-03		
	ND plus	ES/SAF/FAS	VISIT 11	2020-03-19		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2017-03-13		
08/0803	ND basic	ES/SAF/FAS	VISIT 1	2015-02-24		
	ND basic	ES/SAF/FAS	VISIT 2A	2015-02-24		
	ND basic	ES/SAF/FAS	VISIT 2B	2015-02-25		
	ND basic	ES/SAF/FAS	VISIT 3A	2015-06-15		
	ND basic	ES/SAF/FAS	VISIT 3B	2015-06-16		
	ND basic	ES/SAF/FAS	VISIT 4	2015-07-24		
	ND basic	ES/SAF/FAS	VISIT 5	2015-09-07		
	ND basic	ES/SAF/FAS	END OF TRIAL		2015-11-04	Lack of compliance
08/0804	ND plus	ES/SAF/FAS	VISIT 1	2015-06-02		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-06-02		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-06-03		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-08-20		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-08-21		
	ND plus	ES/SAF/FAS	VISIT 4	2015-09-28		
	ND plus	ES/SAF/FAS	VISIT 5	2015-11-13		
	ND plus	ES/SAF/FAS	VISIT 6	2016-02-05		
	ND plus	ES/SAF/FAS	VISIT 7	2016-08-22		
	ND plus	ES/SAF/FAS	VISIT 8	2017-08-04		
	ND plus	ES/SAF/FAS	VISIT 9	2018-08-27		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
08/0804	ND plus	ES/SAF/FAS	VISIT 10	2019-08-05		
	ND plus	ES/SAF/FAS	VISIT 11	2020-08-04		
	ND plus	ES/SAF/FAS	END OF TRIAL			
08/0805	ND basic	ES/SAF/FAS	VISIT 1	2015-06-19		
	ND basic	ES/SAF/FAS	VISIT 2A	2015-06-24		
	ND basic	ES/SAF/FAS	VISIT 2B	2015-06-25		
	ND basic	ES/SAF/FAS	VISIT 3A	2015-09-21		
	ND basic	ES/SAF/FAS	VISIT 3B	2015-09-22		
	ND basic	ES/SAF/FAS	VISIT 4	2015-11-02		
	ND basic	ES/SAF/FAS	VISIT 5	2015-12-21		
	ND basic	ES/SAF/FAS	VISIT 6	2016-03-07		
	ND basic	ES/SAF/FAS	VISIT 7	2017-02-14		
	ND basic	ES/SAF/FAS	VISIT 8	2017-08-28		
	ND basic	ES/SAF/FAS	VISIT 9	2018-09-07		
	ND basic	ES/SAF/FAS	VISIT 10	2019-09-24		
	ND basic	ES/SAF/FAS	VISIT 11	2020-09-03		
	ND basic	ES/SAF/FAS	END OF TRIAL			
	ND basic	ES/SAF/FAS	UNSCHEDULED	2016-06-24		
	ND basic	ES/SAF/FAS	UNSCHEDULED	2016-07-28		
08/0806	ND plus	ES/SAF/FAS	VISIT 1	2015-07-07		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-07-07		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-07-08		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-09-28		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-09-29		
	ND plus	ES/SAF/FAS	VISIT 4	2015-11-06		
	ND plus	ES/SAF/FAS	VISIT 5	2015-12-23		
	ND plus	ES/SAF/FAS	VISIT 6	2016-03-14		
	ND plus	ES/SAF/FAS	VISIT 7	2016-09-27		
	ND plus	ES/SAF/FAS	VISIT 8	2017-10-12		
	ND plus	ES/SAF/FAS	VISIT 9	2018-09-27		
	ND plus	ES/SAF/FAS	VISIT 10	2019-09-16		
	ND plus	ES/SAF/FAS	VISIT 11	2020-09-24		
	ND plus	ES/SAF/FAS	END OF TRIAL			
08/0807	ND plus	ES/SAF/FAS	VISIT 1	2015-11-18		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-11-18		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
08/0807	ND plus	ES/SAF/FAS	VISIT 2B	2015-11-19		
	ND plus	ES/SAF/FAS	VISIT 3A	2016-02-01		
	ND plus	ES/SAF/FAS	VISIT 3B	2016-02-02		
	ND plus	ES/SAF/FAS	VISIT 4	2016-03-08		
	ND plus	ES/SAF/FAS	VISIT 5	2016-05-03		
	ND plus	ES/SAF/FAS	VISIT 6	2016-07-28		
	ND plus	ES/SAF/FAS	VISIT 7	2017-02-06		
	ND plus	ES/SAF/FAS	VISIT 8	2018-02-19		
	ND plus	ES/SAF/FAS	END OF TRIAL		2018-02-19	Lack of compliance
	ND plus	ES/SAF/FAS	UNSCHEDULED	2016-03-16		
08/0808	SC	ES/SAF/FAS	VISIT 1	2015-12-02		
	SC	ES/SAF/FAS	VISIT 2A	2015-12-02		
	SC	ES/SAF/FAS	VISIT 2B	2015-12-03		
	SC	ES/SAF/FAS	VISIT 4	2016-01-07		
	SC	ES/SAF/FAS	VISIT 5	2016-02-26		
	SC	ES/SAF/FAS	VISIT 6	2016-06-03		
	SC	ES/SAF/FAS	VISIT 7	2016-11-28		
	SC	ES/SAF/FAS	VISIT 8	2017-11-13		
	SC	ES/SAF/FAS	VISIT 9	2018-12-19		
	SC	ES/SAF/FAS	VISIT 10	2019-12-22		
	SC	ES/SAF/FAS	VISIT 11	2021-04-13		
	SC	ES/SAF/FAS	END OF TRIAL			
09/0901	SC	ES/SAF/FAS	VISIT 1	2014-10-27		
	SC	ES/SAF/FAS	VISIT 2A	2014-10-29		
	SC	ES/SAF/FAS	VISIT 2B	2014-10-30		
	SC	ES/SAF/FAS	VISIT 4	2014-12-08		
	SC	ES/SAF/FAS	VISIT 5	2015-01-27		
	SC	ES/SAF/FAS	VISIT 6	2015-05-05		
	SC	ES/SAF/FAS	VISIT 7	2015-11-03		
	SC	ES/SAF/FAS	VISIT 8	2016-11-22		
	SC	ES/SAF/FAS	VISIT 9	2017-10-19		
	SC	ES/SAF/FAS	VISIT 10	2018-10-18		
	SC	ES/SAF/FAS	VISIT 11	2019-10-28		
	SC	ES/SAF/FAS	END OF TRIAL			
09/0902		ES	VISIT 1	2014-11-12	2014-11-12	Inclusion/Exclusion criteria not met

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
09/0903	ND plus	ES/SAF	VISIT 1	2014-11-19		
	ND plus	ES/SAF	VISIT 2A	2014-11-19		
	ND plus	ES/SAF	VISIT 2B	2014-11-20		
	ND plus	ES/SAF	VISIT 3A	2015-02-11		
	ND plus	ES/SAF	VISIT 3B	2015-02-11		
	ND plus	ES/SAF	END OF TRIAL		2015-02-11	Other reason
09/0904	ND basic	ES/SAF/FAS	VISIT 1	2015-02-05		
	ND basic	ES/SAF/FAS	VISIT 2A	2015-02-05		
	ND basic	ES/SAF/FAS	VISIT 2B	2015-02-09		
	ND basic	ES/SAF/FAS	VISIT 3A	2015-05-20		
	ND basic	ES/SAF/FAS	VISIT 3B	2015-05-21		
	ND basic	ES/SAF/FAS	VISIT 4	2015-07-08		
	ND basic	ES/SAF/FAS	VISIT 5	2015-08-26		
	ND basic	ES/SAF/FAS	VISIT 6	2015-11-17		
	ND basic	ES/SAF/FAS	VISIT 7	2016-05-23		
	ND basic	ES/SAF/FAS	VISIT 8	2017-04-24		
	ND basic	ES/SAF/FAS	VISIT 9	2018-05-07		
	ND basic	ES/SAF/FAS	VISIT 10	2019-05-20		
	ND basic	ES/SAF/FAS	VISIT 11	2020-05-11		
	ND basic	ES/SAF/FAS	END OF TRIAL			
09/0905	ND plus	ES/SAF/FAS	VISIT 1	2015-03-18		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-03-18		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-03-19		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-06-24		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-06-25		
	ND plus	ES/SAF/FAS	VISIT 4	2015-08-10		
	ND plus	ES/SAF/FAS	VISIT 5	2015-09-28		
	ND plus	ES/SAF/FAS	VISIT 6	2015-12-21		
	ND plus	ES/SAF/FAS	VISIT 7	2016-06-20		
	ND plus	ES/SAF/FAS	VISIT 8	2017-06-19		
	ND plus	ES/SAF/FAS	VISIT 9	2018-06-20		
	ND plus	ES/SAF/FAS	VISIT 10	2019-06-24		
	ND plus	ES/SAF/FAS	VISIT 11	2020-05-25		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2018-09-26		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2019-02-20		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
09/0905	ND plus	ES/SAF/FAS	UNSCHEDULED	2019-03-13		
09/0906		ES	VISIT 1	2015-03-26	2015-03-26	Inclusion/Exclusion criteria not met
09/0907	SC	ES/SAF/FAS	VISIT 1	2015-04-13		
	SC	ES/SAF/FAS	VISIT 2A	2015-04-13		
	SC	ES/SAF/FAS	VISIT 2B	2015-04-15		
	SC	ES/SAF/FAS	VISIT 4	2015-05-26		
	SC	ES/SAF/FAS	VISIT 5	2015-07-14		
	SC	ES/SAF/FAS	VISIT 6	2015-11-09		
	SC	ES/SAF/FAS	VISIT 7	2016-04-04		
	SC	ES/SAF/FAS	VISIT 8	2017-04-10		
	SC	ES/SAF/FAS	VISIT 9	2018-04-16		
	SC	ES/SAF/FAS	VISIT 10	2019-05-13		
	SC	ES/SAF/FAS	VISIT 11	2020-05-12		
	SC	ES/SAF/FAS	END OF TRIAL			
09/0908	ND basic	ES/SAF/FAS	VISIT 1	2015-05-05		
	ND basic	ES/SAF/FAS	VISIT 2A	2015-05-05		
	ND basic	ES/SAF/FAS	VISIT 2B	2015-05-07		
	ND basic	ES/SAF/FAS	VISIT 3A	2015-08-05		
	ND basic	ES/SAF/FAS	VISIT 3B	2015-08-06		
	ND basic	ES/SAF/FAS	VISIT 4	2015-09-21		
	ND basic	ES/SAF/FAS	VISIT 5	2015-11-02		
	ND basic	ES/SAF/FAS	VISIT 6	2016-01-25		
	ND basic	ES/SAF/FAS	VISIT 7	2016-07-20		
	ND basic	ES/SAF/FAS	VISIT 8	2017-07-17		
	ND basic	ES/SAF/FAS	VISIT 9	2018-07-09		
	ND basic	ES/SAF/FAS	VISIT 10	2019-07-09		
	ND basic	ES/SAF/FAS	VISIT 11	2020-06-22		
	ND basic	ES/SAF/FAS	END OF TRIAL			
09/0909	ND plus	ES/SAF/FAS	VISIT 1	2015-05-11		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-05-11		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-05-12		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-08-12		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-08-13		
	ND plus	ES/SAF/FAS	VISIT 4	2015-09-28		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
09/0909	ND plus	ES/SAF/FAS	VISIT 5	2015-11-09		
	ND plus	ES/SAF/FAS	VISIT 6	2016-02-01		
	ND plus	ES/SAF/FAS	VISIT 7	2016-07-18		
	ND plus	ES/SAF/FAS	VISIT 8	2017-07-24		
	ND plus	ES/SAF/FAS	VISIT 9	2018-07-30		
	ND plus	ES/SAF/FAS	VISIT 10	2019-07-29		
	ND plus	ES/SAF/FAS	VISIT 11	2020-07-27		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2015-08-20		
09/0910	ND plus	ES/SAF	VISIT 1	2015-08-31		
	ND plus	ES/SAF	VISIT 2A	2015-08-31		
	ND plus	ES/SAF	VISIT 2B	2015-09-01		
	ND plus	ES/SAF	END OF TRIAL		2015-11-18	Lack of compliance
09/0911	ND plus	ES/SAF/FAS	VISIT 1	2015-10-15		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-10-15		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-10-19		
	ND plus	ES/SAF/FAS	VISIT 3A	2016-01-13		
	ND plus	ES/SAF/FAS	VISIT 3B	2016-01-14		
	ND plus	ES/SAF/FAS	VISIT 4	2016-02-22		
	ND plus	ES/SAF/FAS	VISIT 5	2016-04-11		
	ND plus	ES/SAF/FAS	VISIT 6	2016-07-04		
	ND plus	ES/SAF/FAS	VISIT 7	2017-01-16		
	ND plus	ES/SAF/FAS	VISIT 8	2018-01-29		
	ND plus	ES/SAF/FAS	VISIT 9	2019-01-21		
	ND plus	ES/SAF/FAS	VISIT 10	2020-02-10		
	ND plus	ES/SAF/FAS	VISIT 11	2021-01-18		
	ND plus	ES/SAF/FAS	END OF TRIAL			
09/0912	ND plus	ES/SAF/FAS	VISIT 1	2015-10-19		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-10-19		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-10-20		
	ND plus	ES/SAF/FAS	VISIT 3A	2016-01-20		
	ND plus	ES/SAF/FAS	VISIT 3B	2016-01-21		
	ND plus	ES/SAF/FAS	VISIT 4	2016-02-29		
	ND plus	ES/SAF/FAS	VISIT 5	2016-04-25		
	ND plus	ES/SAF/FAS	VISIT 6	2016-07-25		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
09/0912	ND plus	ES/SAF/FAS	VISIT 7	2017-01-23		
	ND plus	ES/SAF/FAS	VISIT 8	2018-01-15		
	ND plus	ES/SAF/FAS	VISIT 9	2019-01-21		
	ND plus	ES/SAF/FAS	VISIT 10	2020-01-20		
	ND plus	ES/SAF/FAS	VISIT 11	2021-01-25		
	ND plus	ES/SAF/FAS	END OF TRIAL			
09/0913	ND basic	ES/SAF/FAS	VISIT 1	2015-11-26		
	ND basic	ES/SAF/FAS	VISIT 2A	2015-11-26		
	ND basic	ES/SAF/FAS	VISIT 2B	2015-11-30		
	ND basic	ES/SAF/FAS	VISIT 3A	2016-02-17		
	ND basic	ES/SAF/FAS	VISIT 3B	2016-02-18		
	ND basic	ES/SAF/FAS	VISIT 4	2016-04-04		
	ND basic	ES/SAF/FAS	VISIT 5	2016-05-23		
	ND basic	ES/SAF/FAS	VISIT 6	2016-08-01		
	ND basic	ES/SAF/FAS	VISIT 7	2017-01-30		
	ND basic	ES/SAF/FAS	VISIT 8	2018-02-05		
	ND basic	ES/SAF/FAS	VISIT 9	2019-02-21		
	ND basic	ES/SAF/FAS	VISIT 10	2020-02-16		
	ND basic	ES/SAF/FAS	VISIT 11	2021-03-08		
	ND basic	ES/SAF/FAS	END OF TRIAL			
	ND basic	ES/SAF/FAS	UNSCHEDULED	2015-12-03		
	ND basic	ES/SAF/FAS	UNSCHEDULED	2017-01-25		
09/0914	SC	ES/SAF/FAS	VISIT 1	2016-01-04		
	SC	ES/SAF/FAS	VISIT 2A	2016-01-04		
	SC	ES/SAF/FAS	VISIT 2B	2016-01-06		
	SC	ES/SAF/FAS	VISIT 4	2016-02-15		
	SC	ES/SAF/FAS	VISIT 5	2016-04-11		
	SC	ES/SAF/FAS	VISIT 6	2016-06-27		
	SC	ES/SAF/FAS	VISIT 7	2017-01-09		
	SC	ES/SAF/FAS	VISIT 8	2018-01-08		
	SC	ES/SAF/FAS	VISIT 9	2019-01-07		
	SC	ES/SAF/FAS	VISIT 10	2020-02-25		
	SC	ES/SAF/FAS	VISIT 11	2021-01-11		
	SC	ES/SAF/FAS	END OF TRIAL			
09/0915	ND basic	ES/SAF/FAS	VISIT 1	2016-01-05		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
09/0915	ND basic	ES/SAF/FAS	VISIT 2A	2016-01-05		
	ND basic	ES/SAF/FAS	VISIT 2B	2016-01-06		
	ND basic	ES/SAF/FAS	VISIT 3A	2016-03-23		
	ND basic	ES/SAF/FAS	VISIT 3B	2016-03-24		
	ND basic	ES/SAF/FAS	VISIT 4	2016-05-02		
	ND basic	ES/SAF/FAS	VISIT 5	2016-06-20		
	ND basic	ES/SAF/FAS	VISIT 6	2016-09-26		
	ND basic	ES/SAF/FAS	VISIT 7	2017-04-03		
	ND basic	ES/SAF/FAS	VISIT 8	2018-04-09		
	ND basic	ES/SAF/FAS	VISIT 9	2019-04-01		
	ND basic	ES/SAF/FAS	VISIT 10	2020-03-30		
	ND basic	ES/SAF/FAS	VISIT 11	2021-02-22		
	ND basic	ES/SAF/FAS	END OF TRIAL			
	ND basic	ES/SAF/FAS	UNSCHEDULED	2016-12-21		
	ND basic	ES/SAF/FAS	UNSCHEDULED	2020-07-23		
09/0916	SC	ES/SAF/FAS	VISIT 1	2016-02-22		
	SC	ES/SAF/FAS	VISIT 2A	2016-02-22		
	SC	ES/SAF/FAS	VISIT 2B	2016-02-23		
	SC	ES/SAF/FAS	VISIT 4	2016-04-06		
	SC	ES/SAF/FAS	VISIT 5	2016-05-30		
	SC	ES/SAF/FAS	VISIT 6	2016-08-29		
	SC	ES/SAF/FAS	VISIT 7	2017-02-20		
	SC	ES/SAF/FAS	VISIT 8	2018-02-26		
	SC	ES/SAF/FAS	VISIT 9	2019-02-25		
	SC	ES/SAF/FAS	VISIT 10	2020-02-02		
	SC	ES/SAF/FAS	VISIT 11	2021-03-01		
	SC	ES/SAF/FAS	END OF TRIAL			
10/1001		ES	VISIT 1	2015-11-30	2015-12-02	Inclusion/Exclusion criteria not met
		ES	VISIT 2A	2015-11-30		
11/1101	ND plus	ES/SAF/FAS	VISIT 1	2015-01-12		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-01-12		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-01-13		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-03-30		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-03-31		
	ND plus	ES/SAF/FAS	VISIT 4	2015-05-11		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
11/1101	ND plus	ES/SAF/FAS	VISIT 5	2015-07-03		
	ND plus	ES/SAF/FAS	VISIT 6	2015-10-09		
	ND plus	ES/SAF/FAS	VISIT 7	2016-04-08		
	ND plus	ES/SAF/FAS	VISIT 8	2017-01-24		
	ND plus	ES/SAF/FAS	VISIT 9	2018-03-26		
	ND plus	ES/SAF/FAS	VISIT 10	2019-03-13		
	ND plus	ES/SAF/FAS	VISIT 11	2020-04-21		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2017-09-27		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2019-06-28		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2019-07-30		
11/1102	ND basic	ES/SAF/FAS	VISIT 1	2015-04-15		
	ND basic	ES/SAF/FAS	VISIT 2A	2015-04-20		
	ND basic	ES/SAF/FAS	VISIT 2B	2015-04-20		
	ND basic	ES/SAF/FAS	VISIT 3A	2015-07-27		
	ND basic	ES/SAF/FAS	VISIT 3B	2015-07-28		
	ND basic	ES/SAF/FAS	VISIT 4	2015-09-11		
	ND basic	ES/SAF/FAS	VISIT 5	2015-10-23		
	ND basic	ES/SAF/FAS	VISIT 6	2016-02-05		
	ND basic	ES/SAF/FAS	VISIT 7	2016-07-29		
	ND basic	ES/SAF/FAS	VISIT 8	2017-07-14		
	ND basic	ES/SAF/FAS	VISIT 9	2018-08-22		
	ND basic	ES/SAF/FAS	VISIT 10	2019-07-01		
	ND basic	ES/SAF/FAS	VISIT 11	2020-08-18		
	ND basic	ES/SAF/FAS	END OF TRIAL			
11/1103	SC	ES/SAF/FAS	VISIT 1	2015-07-30		
	SC	ES/SAF/FAS	VISIT 2A	2015-08-03		
	SC	ES/SAF/FAS	VISIT 2B	2015-08-03		
	SC	ES/SAF/FAS	VISIT 4	2015-09-18		
	SC	ES/SAF/FAS	VISIT 5	2015-11-06		
	SC	ES/SAF/FAS	VISIT 6	2016-02-12		
	SC	ES/SAF/FAS	VISIT 7	2016-08-05		
	SC	ES/SAF/FAS	VISIT 8	2017-08-04		
	SC	ES/SAF/FAS	VISIT 9	2018-07-16		
	SC	ES/SAF/FAS	VISIT 10	2019-07-10		
	SC	ES/SAF/FAS	VISIT 11	2020-08-25		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
11/1103	SC	ES/SAF/FAS	END OF TRIAL			
	SC	ES/SAF/FAS	UNSCHEDULED	2018-01-05		
	SC	ES/SAF/FAS	UNSCHEDULED	2018-02-14		
11/1104	ND plus	ES/SAF/FAS	VISIT 1	2016-03-01		
	ND plus	ES/SAF/FAS	VISIT 2A	2016-03-07		
	ND plus	ES/SAF/FAS	VISIT 2B	2016-03-07		
	ND plus	ES/SAF/FAS	VISIT 3A	2016-06-06		
	ND plus	ES/SAF/FAS	VISIT 3B	2016-06-07		
	ND plus	ES/SAF/FAS	VISIT 4	2016-07-22		
	ND plus	ES/SAF/FAS	VISIT 5	2016-09-09		
	ND plus	ES/SAF/FAS	VISIT 6	2016-11-25		
	ND plus	ES/SAF/FAS	VISIT 7	2017-05-30		
	ND plus	ES/SAF/FAS	VISIT 8	2018-06-12		
	ND plus	ES/SAF/FAS	VISIT 9	2019-06-03		
	ND plus	ES/SAF/FAS	VISIT 10	2020-05-27		
	ND plus	ES/SAF/FAS	VISIT 11	2021-05-28		
12/1201	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	VISIT 1	2015-09-04		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-09-04		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-09-07		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-11-30		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-12-01		
	ND plus	ES/SAF/FAS	VISIT 4	2016-01-08		
	ND plus	ES/SAF/FAS	VISIT 5	2016-02-26		
	ND plus	ES/SAF/FAS	VISIT 6	2016-05-18		
	ND plus	ES/SAF/FAS	VISIT 7	2016-11-22		
	ND plus	ES/SAF/FAS	VISIT 8	2017-11-21		
	ND plus	ES/SAF/FAS	VISIT 9	2018-11-20		
	ND plus	ES/SAF/FAS	VISIT 10	2019-12-12		
	ND plus	ES/SAF/FAS	VISIT 11	2020-12-01		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2015-10-22		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2016-05-17		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2016-08-03		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2017-07-06		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2018-06-27		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
12/1202		ES	VISIT 1	2015-10-02	2015-10-02	Inclusion/Exclusion criteria not met
13/1301	ND plus	ES/SAF/FAS	VISIT 1	2015-04-23		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-04-26		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-04-27		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-07-28		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-07-29		
	ND plus	ES/SAF/FAS	VISIT 4	2015-09-08		
	ND plus	ES/SAF/FAS	VISIT 5	2015-10-22		
	ND plus	ES/SAF/FAS	VISIT 6	2016-01-11		
	ND plus	ES/SAF/FAS	VISIT 7	2016-07-20		
	ND plus	ES/SAF/FAS	VISIT 8	2017-06-28		
	ND plus	ES/SAF/FAS	VISIT 9	2018-06-27		
	ND plus	ES/SAF/FAS	VISIT 10	2019-06-28		
	ND plus	ES/SAF/FAS	VISIT 11	2020-06-24		
	ND plus	ES/SAF/FAS	END OF TRIAL			
	ND plus	ES/SAF/FAS	UNSCHEDULED	2015-06-11		
	ND plus	ES/SAF/FAS	UNSCHEDULED	2017-03-22		
13/1302	ND plus	ES/SAF/FAS	VISIT 1	2015-05-11		
	ND plus	ES/SAF/FAS	VISIT 2A	2015-05-11		
	ND plus	ES/SAF/FAS	VISIT 2B	2015-05-12		
	ND plus	ES/SAF/FAS	VISIT 3A	2015-07-28		
	ND plus	ES/SAF/FAS	VISIT 3B	2015-07-29		
	ND plus	ES/SAF/FAS	VISIT 4	2015-09-08		
	ND plus	ES/SAF/FAS	VISIT 5	2015-10-22		
	ND plus	ES/SAF/FAS	VISIT 6	2016-01-11		
	ND plus	ES/SAF/FAS	VISIT 7	2016-07-19		
	ND plus	ES/SAF/FAS	VISIT 8	2017-07-19		
	ND plus	ES/SAF/FAS	VISIT 9	2018-08-28		
	ND plus	ES/SAF/FAS	VISIT 10	2019-06-21		
	ND plus	ES/SAF/FAS	VISIT 11	2020-07-01		
	ND plus	ES/SAF/FAS	END OF TRIAL			
13/1303	SC	ES/SAF/FAS	VISIT 1	2015-06-25		
	SC	ES/SAF/FAS	VISIT 2A	2015-06-28		
	SC	ES/SAF/FAS	VISIT 2B	2015-06-29		
	SC	ES/SAF/FAS	VISIT 4	2015-09-01		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.1: Subject Disposition - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Date of visit	Date of premature study discontinuation	Reason for premature study discontinuation
13/1303	SC	ES/SAF/FAS	VISIT 5	2015-09-29		
	SC	ES/SAF/FAS	VISIT 6	2015-12-14		
	SC	ES/SAF/FAS	VISIT 7	2016-07-06		
	SC	ES/SAF/FAS	VISIT 8	2017-07-12		
	SC	ES/SAF/FAS	VISIT 9	2018-05-29		
	SC	ES/SAF/FAS	VISIT 10	2019-07-11		
	SC	ES/SAF/FAS	VISIT 11	2020-06-03		
	SC	ES/SAF/FAS	END OF TRIAL			
	SC	ES/SAF/FAS	UNSCHEDULED	2017-12-20		
	SC	ES/SAF/FAS	UNSCHEDULED	2020-06-17		
13/1304	ND basic	ES/SAF/FAS	VISIT 1	2015-06-28		
	ND basic	ES/SAF/FAS	VISIT 2A	2015-07-01		
	ND basic	ES/SAF/FAS	VISIT 2B	2015-07-02		
	ND basic	ES/SAF/FAS	VISIT 3A	2015-09-15		
	ND basic	ES/SAF/FAS	VISIT 3B	2015-09-18		
	ND basic	ES/SAF/FAS	VISIT 4	2015-11-02		
	ND basic	ES/SAF/FAS	VISIT 5	2015-12-14		
	ND basic	ES/SAF/FAS	VISIT 6	2016-04-01		
	ND basic	ES/SAF/FAS	VISIT 7	2016-09-14		
	ND basic	ES/SAF/FAS	VISIT 8	2017-09-06		
	ND basic	ES/SAF/FAS	VISIT 9	2018-09-06		
	ND basic	ES/SAF/FAS	VISIT 10	2019-08-23		
	ND basic	ES/SAF/FAS	VISIT 11	2020-09-02		
	ND basic	ES/SAF/FAS	END OF TRIAL			
	ND basic	ES/SAF/FAS	UNSCHEDULED	2015-08-18		
	ND basic	ES/SAF/FAS	UNSCHEDULED	2015-11-17		
	ND basic	ES/SAF/FAS	UNSCHEDULED	2016-07-27		
	ND basic	ES/SAF/FAS	UNSCHEDULED	2018-05-30		
13/1305	ND plus	ES/SAF	VISIT 1	2015-10-13		
	ND plus	ES/SAF	VISIT 2A	2015-10-14		
	ND plus	ES/SAF	VISIT 2B	2015-10-15		
	ND plus	ES/SAF	END OF TRIAL		2015-11-26	Withdrawal of clinical trial subject's consent

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

* Visits V3a and V3b only applicable for patients in Ndbasic and Ndplus group

Clinipace: 14DEC21 / 7:42 / l_disp.lst / l_disp.sas

Listing 16.2.1.2: Demographic data - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Sex	Age (years)	Race	Hispanic origin or Latino	Height (cm) at baseline	Weight (kg) at baseline	BMI (kg/m ²) at baseline
01/0102		ES	Male	53	White		-	-	-
01/0103	ND basic	ES/SAF/FAS	Male	52	White	No	172	82	27.718
01/0104	ND basic	ES/SAF/FAS	Male	31	White	No	180	78	24.074
01/0105		ES	Female	38	White		-	-	-
01/0106	ND plus	ES/SAF/FAS	Male	48	White	No	180	84	25.926
01/0107	ND plus	ES/SAF/FAS	Male	50	White	No	170	75	25.952
01/0108	ND plus	ES/SAF/FAS	Male	37	White	No	195	95	24.984
01/0109		ES	Male	41	White		-	-	-
01/0110	ND basic	ES/SAF/FAS	Female	50	White	No	160	58	22.656
01/0111	ND plus	ES/SAF/FAS	Male	52	White	No	187	93	26.595
01/0112	ND basic	ES/SAF	Female	26	White	No	157	70	28.399
01/0113	ND basic	ES/SAF/FAS	Male	45	White	No	180	85	26.235
01/0114	ND basic	ES/SAF/FAS	Female	36	White	No	176	67	21.630
01/0115	ND plus	ES/SAF/FAS	Male	44	White	No	180	75	23.148
01/0116	ND basic	ES/SAF	Male	26	White	No	184	67	19.790
01/0117		ES	Male	48	White		-	-	-
01/0118	ND plus	ES/SAF/FAS	Male	47	White	No	183	85	25.381
01/0119	ND basic	ES/SAF/FAS	Male	51	White	No	176	83	26.795
01/0120		ES	Female	35	White	Yes	-	-	-
01/0121	ND plus	ES/SAF/FAS	Male	29	White	No	189	89	24.915
01/0122	ND plus	ES/SAF/FAS	Male	49	White	No	173	68	22.720
01/0123	ND plus	ES/SAF/FAS	Male	50	White	No	174	88	29.066
01/0124	ND plus	ES/SAF	Male	29	White	No	175	72	23.510
01/0125	SC	ES/SAF/FAS	Male	45	White	No	179	65	20.287
01/0126	ND basic	ES/SAF/FAS	Female	38	White	No	167	60	21.514
01/0127	ND plus	ES/SAF/FAS	Male	36	White	No	178	74	23.356
01/0128	ND plus	ES/SAF/FAS	Male	24	White	No	184	86	25.402
01/0129	SC	ES/SAF/FAS	Male	47	White	No	175	86	28.082
01/0130	ND basic	ES/SAF/FAS	Female	49	White	No	168	80	28.345
01/0131	ND plus	ES/SAF/FAS	Male	32	White	No	177	67	21.386
01/0132	SC	ES/SAF/FAS	Male	25	White	No	191	82	22.477
01/0133	ND plus	ES/SAF	Female	52	White	No	168	76	26.927
01/0134	ND basic	ES/SAF	Male	29	White	No	175	72	23.510
01/0135	ND plus	ES/SAF/FAS	Female	53	White	No	163	54	20.324
01/0136	ND basic	ES/SAF/FAS	Male	46	White	No	189	105	29.394
01/0137	ND plus	ES/SAF/FAS	Female	49	White	No	163	53	19.948
01/0138	SC	ES/SAF/FAS	Male	37	White	No	180	82	25.309
01/0139	ND plus	ES/SAF/FAS	Male	29	White	No	186	100	28.905
01/0140	ND basic	ES/SAF/FAS	Male	49	White	No	176	74	23.889
01/0141	SC	ES/SAF/FAS	Female	27	White	No	170	73	25.260

Listing 16.2.1.2: Demographic data - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Sex	Age (years)	Race	Hispanic origin or Latino	Height (cm) at baseline	Weight (kg) at baseline	BMI (kg/m ²) at baseline
01/0142	ND plus	ES/SAF/FAS	Female	46	White	No	165	58	21.304
01/0143	ND plus	ES/SAF/FAS	Male	44	White	No	192	92	24.957
01/0144	ND basic	ES/SAF/FAS	Male	36	White	No	180	78	24.074
01/0145	ND plus	ES/SAF/FAS	Female	31	White	No	172	75	25.352
01/0146	SC	ES/SAF/FAS	Male	50	White	No	173	85	28.401
01/0147	ND plus	ES/SAF/FAS	Female	44	White	No	164	66	24.539
01/0148	ND plus	ES/SAF/FAS	Male	54	White	No	182	79	23.850
01/0149	ND plus	ES/SAF/FAS	Female	51	White	No	164	75	27.885
01/0150		ES	Female	45	White	No	168	56	19.841
01/0151	ND basic	ES/SAF/FAS	Male	25	White	No	190	105	29.086
01/0152	SC	ES/SAF/FAS	Female	55	White	No	160	49	19.141
01/0153	ND basic	ES/SAF/FAS	Female	24	White	No	169	72	25.209
02/0201	ND plus	ES/SAF/FAS	Female	43	White	No	176	76	24.535
02/0202	ND basic	ES/SAF	Female	47	White	No	175	78	25.469
02/0203	ND basic	ES/SAF/FAS	Male	50	White	No	188	91	25.747
02/0204	ND basic	ES/SAF	Male	35	White	No	185	75	21.914
02/0205	ND basic	ES/SAF/FAS	Male	45	White	No	180	90	27.778
02/0206	ND plus	ES/SAF/FAS	Male	46	White	No	183	80	23.888
02/0207		ES	Male	34	White	No	183	94	28.069
02/0208	ND plus	ES/SAF/FAS	Male	45	White	No	186	62	17.921
02/0209	ND plus	ES/SAF/FAS	Male	25	White	No	178	82	25.881
02/0210		ES	Male	32	White	No	170	103	35.640
02/0211	ND basic	ES/SAF	Male	28	White	No	193	71	19.061
02/0212	SC	ES/SAF/FAS	Male	36	White	No	185	100	29.218
02/0213	ND plus	ES/SAF	Female	21	White	No	167	64	22.948
02/0214	ND plus	ES/SAF/FAS	Female	26	White	No	160	66	25.781
02/0215		ES	Male	32	White	No	186	96	27.749
02/0216	ND plus	ES/SAF/FAS	Female	37	White	No	172	85	28.732
02/0217	SC	ES/SAF/FAS	Male	29	White	No	185	93.5	27.319
02/0218	ND basic	ES/SAF	Female	55	White	No	163	63	23.712
02/0219	ND basic	ES/SAF/FAS	Female	24	White	No	167	72	25.817
02/0220	SC	ES/SAF/FAS	Female	44	White	No	158	88	35.251
02/0221	ND plus	ES/SAF	Female	48	White	No	164	61	22.680
02/0222	ND plus	ES/SAF	Male	42	White	No	180	103	31.790
02/0223	ND basic	ES/SAF/FAS	Female	57	White	No	158	58	23.233
02/0224	ND plus	ES/SAF	Female	35	White	No	169	55	19.257
04/0401	SC	ES/SAF/FAS	Male	39	White	No	172	72	24.337

Listing 16.2.1.2: Demographic data - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Sex	Age (years)	Race	Hispanic origin or Latino	Height (cm) at baseline	Weight (kg) at baseline	BMI (kg/m ²) at baseline
06/0601		ES	Female	61	White		-	-	-
06/0602	ND plus	ES/SAF/FAS	Female	54	White	No	164	67	24.911
06/0604	ND basic	ES/SAF	Male	34	White	No	190	90	24.931
06/0605	ND plus	ES/SAF	Male	51	White	No	187	99	28.311
06/0606	SC	ES/SAF/FAS	Female	38	White	No	160	85	33.203
06/0607	ND plus	ES/SAF/FAS	Female	59	White	No	160	75	29.297
06/0608	SC	ES/SAF	Male	45	White	No	175	82	26.776
06/0609	ND basic	ES/SAF	Female	22	White	No	165	70	25.712
06/0610	ND plus	ES/SAF/FAS	Female	31	White	No	164	69	25.654
06/0611		ES	Male	39	White	No	180	85	26.235
06/0612	ND plus	ES/SAF/FAS	Male	58	White	No	185	85	24.836
06/0613	SC	ES/SAF/FAS	Male	51	White	No	178	81	25.565
06/0614	ND plus	ES/SAF/FAS	Male	30	White	No	187	75	21.448
06/0615	ND basic	ES/SAF	Male	40	White	No	175	70	22.857
06/0616		ES	Male	45	White	No	171	90	30.779
06/0617	ND plus	ES/SAF	Male	33	White	No	180	87	26.852
06/0618		ES	Male	36	White	No	178	86	27.143
06/0619	ND basic	ES/SAF/FAS	Male	55	White	No	190	109	30.194
06/0620	SC	ES/SAF/FAS	Male	27	White	No	185	105	30.679
07/0701	ND plus	ES/SAF/FAS	Female	27	White	No	164	50	18.590
07/0702	SC	ES/SAF/FAS	Female	32	White	No	170	70	24.221
07/0703	ND plus	ES/SAF/FAS	Female	35	White	No	178	73	23.040
07/0704	ND basic	ES/SAF/FAS	Female	52	White	No	170	73	25.260
07/0705		ES	Male	35	White	No	179	74	23.095
07/0706	SC	ES/SAF/FAS	Male	37	White	No	184	110	32.491
07/0707		ES	Female	26	White	No	164	68	25.283
08/0801	SC	ES/SAF/FAS	Female	51	White	No	175	62	20.245
08/0802	ND plus	ES/SAF/FAS	Female	53	White	No	158	55	22.032
08/0803	ND basic	ES/SAF/FAS	Male	51	White	No	193	91	24.430
08/0804	ND plus	ES/SAF/FAS	Male	49	White	No	198	115	29.334
08/0805	ND basic	ES/SAF/FAS	Female	47	White	No	166	-	-
08/0806	ND plus	ES/SAF/FAS	Female	54	White	No	180	77	23.765
08/0807	ND plus	ES/SAF/FAS	Female	48	White	No	172	56	18.929
08/0808	SC	ES/SAF/FAS	Male	57	White	No	180	80	24.691
09/0901	SC	ES/SAF/FAS	Male	48	White	No	185	83	24.251
09/0902		ES	Female	51	White	No	165	66	24.242
09/0903	ND plus	ES/SAF	Male	54	White	No	179	81	25.280

Listing 16.2.1.2: Demographic data - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Sex	Age (years)	Race	Hispanic origin or Latino	Height (cm) at baseline	Weight (kg) at baseline	BMI (kg/m ²) at baseline
09/0904	ND basic	ES/SAF/FAS	Male	58	White	No	175	90	29.388
09/0905	ND plus	ES/SAF/FAS	Male	53	White	No	171	67	22.913
09/0906		ES	Female	51	White	No	168	56	19.841
09/0907	SC	ES/SAF/FAS	Male	58	White	No	189	82	22.956
09/0908	ND basic	ES/SAF/FAS	Male	48	White	No	180	85	26.235
09/0909	ND plus	ES/SAF/FAS	Female	53	White	No	175	70	22.857
09/0910	ND plus	ES/SAF	Male	54	White	No	183	112	33.444
09/0911	ND plus	ES/SAF/FAS	Female	26	White	Yes	170	88	30.450
09/0912	ND plus	ES/SAF/FAS	Male	40	White	No	186	86	24.858
09/0913	ND basic	ES/SAF/FAS	Female	28	White	No	178	73	23.040
09/0914	SC	ES/SAF/FAS	Male	35	White	No	182	80	24.152
09/0915	ND basic	ES/SAF/FAS	Male	48	White	No	182	92	27.774
09/0916	SC	ES/SAF/FAS	Male	57	White	No	188	88	24.898
10/1001		ES	Female	57	White	No	161	61	23.533
11/1101	ND plus	ES/SAF/FAS	Female	36	White	No	170	65	22.491
11/1102	ND basic	ES/SAF/FAS	Male	23	White	No	188	75	21.220
11/1103	SC	ES/SAF/FAS	Female	41	White	No	166	80	29.032
11/1104	ND plus	ES/SAF/FAS	Male	43	White	No	188	96	27.162
12/1201	ND plus	ES/SAF/FAS	Female	55	White	No	169	77	26.960
12/1202		ES	Male	59	White	No	168	78	27.636
13/1301	ND plus	ES/SAF/FAS	Female	46	White	No	168	65	23.030
13/1302	ND plus	ES/SAF/FAS	Male	30	White	No	191	100	27.412
13/1303	SC	ES/SAF/FAS	Male	31	White	No	188	72	20.371
13/1304	ND basic	ES/SAF/FAS	Male	33	White	No	190	92	25.485
13/1305	ND plus	ES/SAF	Female	47	White	No	173	68	22.720

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
01/0102		ES			-	-	-	-
01/0103	ND basic	ES/SAF/FAS	VISIT 2A	Yes	-	-	-	1
	ND basic	ES/SAF/FAS	VISIT 3A	Yes	-	-	-	1
	ND basic	ES/SAF/FAS	VISIT 3L	Yes	-	-	-	1
	ND basic	ES/SAF/FAS	VISIT 4	Yes	-	-	-	1
	ND basic	ES/SAF/FAS	VISIT 5	No	-	-	-	-
	ND basic	ES/SAF/FAS	VISIT 6	No	-	-	-	-
	ND basic	ES/SAF/FAS	VISIT 7	No	-	-	-	-
	ND basic	ES/SAF/FAS	VISIT 8	No	-	-	-	-
	ND basic	ES/SAF/FAS	VISIT 9	No	-	-	-	-
	ND basic	ES/SAF/FAS	VISIT 10	No	-	-	-	-
	ND basic	ES/SAF/FAS	VISIT 11	No	-	-	-	-
01/0104	ND basic	ES/SAF/FAS	VISIT 2A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3L	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	No	0	0	0	-
01/0105		ES			-	-	-	-
01/0106	ND plus	ES/SAF/FAS	VISIT 2A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3L	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
01/0107	ND plus	ES/SAF/FAS	VISIT 2A	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	Yes	15	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3L	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	Yes	15	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	Yes	15	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	Yes	15	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	Yes	15	-	-	-
01/0108	ND plus	ES/SAF/FAS	VISIT 2A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3L	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
01/0109		ES			-	-	-	-
01/0110	ND basic	ES/SAF/FAS	VISIT 2A	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3L	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	Yes	2	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	Yes	5	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	Yes	10	0	0	-
01/0111	ND plus	ES/SAF/FAS	VISIT 2A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
01/0111	ND plus	ES/SAF/FAS	VISIT 3L	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
01/0112	ND basic	ES/SAF	VISIT 2A	No	0	0	0	-
	ND basic	ES/SAF	VISIT 11	No	0	0	0	-
	ND basic	ES/SAF	UNSCHEDULED	No	0	0	0	-
01/0113	ND basic	ES/SAF/FAS	VISIT 2A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3L	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
01/0114	ND basic	ES/SAF/FAS	VISIT 2A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3L	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
01/0114	ND basic	ES/SAF/FAS	VISIT 11	No	0	0	0	-
01/0115	ND plus	ES/SAF/FAS	VISIT 2A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3L	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
01/0116	ND basic	ES/SAF	VISIT 2A	Yes	6	-	-	-
01/0117		ES			-	-	-	-
01/0118	ND plus	ES/SAF/FAS	VISIT 2A	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3L	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	Yes	3	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	20	0	0	-
01/0119	ND basic	ES/SAF/FAS	VISIT 2A	Yes	12	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	Yes	20	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
01/0119	ND basic	ES/SAF/FAS	VISIT 3L	Yes	15	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	Yes	15	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	Yes	15	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	Yes	20	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	Yes	15	-	-	-
	ND basic	ES/SAF/FAS	VISIT 8	No	0	-	-	-
	ND basic	ES/SAF/FAS	VISIT 9	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	Yes	15	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	Yes	20	0	0	-
01/0120		ES			-	-	-	-
01/0121	ND plus	ES/SAF/FAS	VISIT 2A	Yes	6	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	Yes	10	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3L	Yes	5	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	Yes	1	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
01/0122	ND plus	ES/SAF/FAS	VISIT 2A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3L	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
01/0123	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
01/0123	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
01/0124	ND plus	ES/SAF	VISIT 1	Yes	15	0	0	-
01/0125	SC	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	SC	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
01/0126	ND basic	ES/SAF/FAS	VISIT 1	Yes	2	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	Yes	2	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	Yes	5	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	Yes	5	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	Yes	5	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	Yes	5	-	-	-
	ND basic	ES/SAF/FAS	VISIT 11	Yes	5	-	-	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
01/0127	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
01/0127	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
01/0128	ND plus	ES/SAF/FAS	VISIT 1	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
01/0129	SC	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	SC	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
01/0130	ND basic	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
01/0131	ND plus	ES/SAF/FAS	VISIT 1	Yes	10	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	Yes	10	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	Yes	10	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	Yes	10	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	Yes	10	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	Yes	10	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	Yes	10	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	Yes	10	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	Yes	5	-	-	-
	ND plus	ES/SAF/FAS	VISIT 11	Yes	5	-	-	-
01/0132	SC	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 11	No	0	0	0	-
01/0133	ND plus	ES/SAF	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF	UNSCHEDULED	No	0	0	0	-
01/0134	ND basic	ES/SAF	VISIT 1	Yes	10	-	-	-
	ND basic	ES/SAF	UNSCHEDULED	Yes	10	-	-	-
01/0135	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
01/0136	ND basic	ES/SAF/FAS	VISIT 1	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	Yes	10	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
01/0136	ND basic	ES/SAF/FAS	VISIT 4	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	Yes	10	0	0	-
01/0137	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
01/0138	SC	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 11	No	0	0	0	-
01/0139	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
01/0139	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
01/0140	ND basic	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	No	0	0	0	-
01/0141	SC	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	SC	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
01/0142	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
01/0143	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
01/0143	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
01/0144	ND basic	ES/SAF/FAS	VISIT 1	Yes	20	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	Yes	15	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	Yes	15	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	Yes	15	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	Yes	15	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	Yes	15	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	Yes	15	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	Yes	15	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	Yes	15	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	Yes	15	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	Yes	15	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	Yes	15	0	0	-
01/0145	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
01/0146	SC	ES/SAF/FAS	VISIT 1	Yes	5	0	0	-
	SC	ES/SAF/FAS	VISIT 4	Yes	5	0	0	-
	SC	ES/SAF/FAS	VISIT 5	Yes	5	0	0	-
	SC	ES/SAF/FAS	VISIT 6	Yes	4	0	0	-
	SC	ES/SAF/FAS	VISIT 7	Yes	4	0	0	-
	SC	ES/SAF/FAS	VISIT 8	Yes	4	0	0	-
	SC	ES/SAF/FAS	VISIT 9	Yes	4	0	0	-
	SC	ES/SAF/FAS	VISIT 10	Yes	4	0	0	-
	SC	ES/SAF/FAS	VISIT 11	Yes	4	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
01/0147	ND plus	ES/SAF/FAS	VISIT 1	Yes	10	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	Yes	15	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	Yes	20	0	0	-
01/0148	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
01/0149	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
01/0150		ES	VISIT 1	No	0	0	0	-
01/0151	ND basic	ES/SAF/FAS	VISIT 1	Yes	20	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	Yes	15	-	-	-
	ND basic	ES/SAF/FAS	VISIT 4	Yes	15	-	-	-
	ND basic	ES/SAF/FAS	VISIT 5	Yes	20	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
01/0151	ND basic	ES/SAF/FAS	VISIT 6	Yes	20	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	Yes	20	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	Yes	1	-	-	-
	ND basic	ES/SAF/FAS	VISIT 9	No	-	-	-	-
	ND basic	ES/SAF/FAS	VISIT 10	No	-	-	-	-
	ND basic	ES/SAF/FAS	VISIT 11	No	-	-	-	-
01/0152	SC	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 10	No	0	0	0	-
01/0153	ND basic	ES/SAF/FAS	VISIT 1	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	Yes	7	-	-	-
	ND basic	ES/SAF/FAS	VISIT 9	Yes	10	-	-	-
	ND basic	ES/SAF/FAS	VISIT 10	Yes	10	-	-	-
	ND basic	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	Yes	10	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	Yes	7	-	-	-
02/0201	ND plus	ES/SAF/FAS	VISIT 2A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3L	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
02/0201	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
02/0201	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
02/0202	ND basic	ES/SAF	VISIT 2A	No	0	0	0	-
02/0203	ND basic	ES/SAF/FAS	VISIT 2A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3L	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
02/0204	ND basic	ES/SAF	VISIT 2A	No	0	0	0	-
02/0205	ND basic	ES/SAF/FAS	VISIT 2A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3L	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	No	0	0	0	-
02/0206	ND plus	ES/SAF/FAS	VISIT 2A	Yes	5	-	-	-
	ND plus	ES/SAF/FAS	VISIT 3A	Yes	3	-	-	-
	ND plus	ES/SAF/FAS	VISIT 3L	Yes	4	-	-	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
02/0206	ND plus	ES/SAF/FAS	VISIT 4	Yes	4	-	-	-
	ND plus	ES/SAF/FAS	VISIT 5	Yes	4	-	-	-
	ND plus	ES/SAF/FAS	VISIT 6	Yes	4	-	-	-
	ND plus	ES/SAF/FAS	VISIT 7	Yes	4	-	-	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	Yes	8	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
02/0207		ES	VISIT 2A	No	0	0	0	-
02/0208	ND plus	ES/SAF/FAS	VISIT 2A	Yes	20	-	-	-
	ND plus	ES/SAF/FAS	VISIT 3A	Yes	25	-	-	-
	ND plus	ES/SAF/FAS	VISIT 3L	Yes	20	-	-	-
	ND plus	ES/SAF/FAS	VISIT 4	Yes	20	-	-	-
	ND plus	ES/SAF/FAS	VISIT 5	Yes	20	-	-	-
	ND plus	ES/SAF/FAS	VISIT 6	Yes	20	-	-	-
	ND plus	ES/SAF/FAS	VISIT 7	Yes	20	-	-	-
	ND plus	ES/SAF/FAS	VISIT 8	Yes	20	-	-	-
	ND plus	ES/SAF/FAS	VISIT 9	Yes	20	-	-	-
	ND plus	ES/SAF/FAS	VISIT 10	Yes	20	-	-	-
	ND plus	ES/SAF/FAS	VISIT 11	Yes	20	-	-	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	20	-	-	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	20	-	-	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	20	-	-	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	20	-	-	-
02/0209	ND plus	ES/SAF/FAS	VISIT 1	Yes	12	-	-	-
	ND plus	ES/SAF/FAS	VISIT 3A	Yes	9	-	-	-
	ND plus	ES/SAF/FAS	VISIT 4	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 5	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 6	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 7	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 8	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 9	Yes	8	-	-	-
	ND plus	ES/SAF/FAS	VISIT 10	Yes	8	-	-	-
	ND plus	ES/SAF/FAS	VISIT 11	Yes	8	-	-	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	10	-	-	-
02/0210		ES	VISIT 1	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
02/0211	ND basic	ES/SAF	VISIT 1	No	0	0	0	-
	ND basic	ES/SAF	VISIT 3A	No	0	0	0	-
02/0212	SC	ES/SAF/FAS	VISIT 1	Yes	10	0	0	-
	SC	ES/SAF/FAS	VISIT 4	Yes	10	0	0	-
	SC	ES/SAF/FAS	VISIT 5	Yes	10	0	0	-
	SC	ES/SAF/FAS	VISIT 6	Yes	10	0	0	-
	SC	ES/SAF/FAS	VISIT 7	Yes	10	0	0	-
	SC	ES/SAF/FAS	VISIT 8	Yes	10	0	0	-
	SC	ES/SAF/FAS	VISIT 9	Yes	10	0	0	-
	SC	ES/SAF/FAS	VISIT 10	Yes	10	0	0	-
	SC	ES/SAF/FAS	VISIT 11	Yes	10	0	0	-
02/0213	ND plus	ES/SAF	VISIT 1	Yes	3	-	-	-
02/0214	ND plus	ES/SAF/FAS	VISIT 1	Yes	12	-	-	-
	ND plus	ES/SAF/FAS	VISIT 3A	Yes	12	-	-	-
	ND plus	ES/SAF/FAS	VISIT 4	Yes	12	-	-	-
	ND plus	ES/SAF/FAS	VISIT 6	Yes	12	-	-	-
	ND plus	ES/SAF/FAS	VISIT 7	Yes	12	-	-	-
	ND plus	ES/SAF/FAS	VISIT 9	Yes	12	-	-	-
	ND plus	ES/SAF/FAS	VISIT 11	Yes	12	-	-	-
02/0215		ES	VISIT 1	No	0	0	0	-
02/0216	ND plus	ES/SAF/FAS	VISIT 1	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	20	0	0	-
02/0217	SC	ES/SAF/FAS	VISIT 1	Yes	10	-	-	-
	SC	ES/SAF/FAS	VISIT 4	Yes	10	-	-	-
	SC	ES/SAF/FAS	VISIT 5	Yes	7	-	-	-
	SC	ES/SAF/FAS	VISIT 6	Yes	10	-	-	-
	SC	ES/SAF/FAS	VISIT 7	Yes	10	-	-	-
	SC	ES/SAF/FAS	VISIT 8	Yes	7	-	-	-
	SC	ES/SAF/FAS	VISIT 9	Yes	8	-	-	-
	SC	ES/SAF/FAS	VISIT 10	Yes	8	-	-	-
	SC	ES/SAF/FAS	VISIT 11	Yes	8	-	-	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
02/0218	ND basic	ES/SAF			-	-	-	-
02/0219	ND basic	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	Yes	5	-	-	-
	ND basic	ES/SAF/FAS	VISIT 4	Yes	6	-	-	-
	ND basic	ES/SAF/FAS	VISIT 5	Yes	6	-	-	-
	ND basic	ES/SAF/FAS	VISIT 6	Yes	6	-	-	-
	ND basic	ES/SAF/FAS	VISIT 7	Yes	6	-	-	-
	ND basic	ES/SAF/FAS	VISIT 8	Yes	6	-	-	-
	ND basic	ES/SAF/FAS	VISIT 9	Yes	6	-	-	-
	ND basic	ES/SAF/FAS	VISIT 10	Yes	10	-	-	-
	ND basic	ES/SAF/FAS	VISIT 11	Yes	10	-	-	-
02/0220	SC	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 11	No	0	0	0	-
02/0221	ND plus	ES/SAF	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF	VISIT 3A	No	0	0	0	-
02/0222	ND plus	ES/SAF	VISIT 1	No	0	0	0	-
02/0223	ND basic	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	No	0	0	0	-
02/0224	ND plus	ES/SAF	VISIT 1	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
04/0401	SC	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 11	No	0	0	0	-
06/0601		ES			-	-	-	-
06/0602	ND plus	ES/SAF/FAS	VISIT 2A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
06/0604	ND basic	ES/SAF	VISIT 1	No	0	0	0	-
06/0605	ND plus	ES/SAF	VISIT 1	Yes	0	0	1	-
06/0606	SC	ES/SAF/FAS	VISIT 1	Yes	19	0	0	-
	SC	ES/SAF/FAS	VISIT 4	Yes	19	0	0	-
	SC	ES/SAF/FAS	VISIT 5	Yes	18	0	0	-
	SC	ES/SAF/FAS	VISIT 6	Yes	13	0	0	-
	SC	ES/SAF/FAS	VISIT 7	Yes	23	0	0	-
	SC	ES/SAF/FAS	VISIT 8	Yes	23	0	0	-
	SC	ES/SAF/FAS	VISIT 9	Yes	23	0	0	-
	SC	ES/SAF/FAS	VISIT 10	Yes	23	0	0	-
	SC	ES/SAF/FAS	VISIT 11	Yes	23	0	0	-
06/0607	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
06/0607	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
06/0608	SC	ES/SAF	VISIT 1	Yes	20	0	0	-
06/0609	ND basic	ES/SAF	VISIT 1	Yes	4	0	0	-
06/0610	ND plus	ES/SAF/FAS	VISIT 1	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 7	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	Yes	3	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	10	-	-	-
06/0611		ES	VISIT 1	No	0	0	0	-
06/0612	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
06/0613	SC	ES/SAF/FAS	VISIT 1	Yes	10	0	0	-
	SC	ES/SAF/FAS	VISIT 4	Yes	10	0	0	-
	SC	ES/SAF/FAS	VISIT 5	Yes	10	0	0	-
	SC	ES/SAF/FAS	VISIT 6	Yes	3	-	-	-
	SC	ES/SAF/FAS	VISIT 7	Yes	3	-	-	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
06/0613	SC	ES/SAF/FAS	VISIT 8	Yes	7	-	-	-
	SC	ES/SAF/FAS	VISIT 9	Yes	8	0	0	-
	SC	ES/SAF/FAS	VISIT 10	Yes	10	0	0	-
	SC	ES/SAF/FAS	VISIT 11	Yes	5	0	0	-
06/0614	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
06/0615	ND basic	ES/SAF	VISIT 1	No	0	0	0	-
06/0616		ES	VISIT 1	No	0	0	0	-
06/0617	ND plus	ES/SAF	VISIT 1	Yes	10	0	0	-
	ND plus	ES/SAF	VISIT 3A	Yes	10	0	0	-
06/0618		ES	VISIT 1	Yes	10	-	-	-
06/0619	ND basic	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
06/0620	SC	ES/SAF/FAS	VISIT 1	Yes	10	-	-	-
	SC	ES/SAF/FAS	VISIT 4	Yes	10	-	-	-
	SC	ES/SAF/FAS	VISIT 5	Yes	10	-	-	-
	SC	ES/SAF/FAS	VISIT 6	Yes	10	-	-	-
	SC	ES/SAF/FAS	VISIT 7	Yes	10	-	-	-
	SC	ES/SAF/FAS	VISIT 8	Yes	10	-	-	-
	SC	ES/SAF/FAS	VISIT 9	Yes	12	-	-	-
	SC	ES/SAF/FAS	VISIT 10	Yes	16	-	-	-
	SC	ES/SAF/FAS	VISIT 11	Yes	16	-	-	-
07/0701	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
07/0702	SC	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 6	Yes	4	-	-	-
	SC	ES/SAF/FAS	VISIT 8	Yes	4	-	-	-
	SC	ES/SAF/FAS	VISIT 10	Yes	4	-	-	-
07/0703	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
07/0704	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 1	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
07/0704	ND basic	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	No	0	0	0	-
07/0705		ES	VISIT 1	Yes	7	0	0	-
07/0706	SC	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 4	No	0	0	0	-
07/0707		ES	VISIT 1	No	0	0	0	-
08/0801	SC	ES/SAF/FAS	VISIT 1	Yes	15	0	0	-
	SC	ES/SAF/FAS	VISIT 4	Yes	15	0	0	-
	SC	ES/SAF/FAS	VISIT 5	Yes	15	0	0	-
	SC	ES/SAF/FAS	VISIT 6	Yes	15	0	0	-
08/0802	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	Yes	20	-	-	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	-	-	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	-	-	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	-	-	-
08/0803	ND basic	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	No	0	0	0	-
08/0804	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
08/0804	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
08/0805	ND basic	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
08/0806	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
08/0807	ND plus	ES/SAF/FAS	VISIT 1	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 3A	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 4	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 5	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 6	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 7	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 8	Yes	10	-	-	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
08/0807	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	10	-	-	-
08/0808	SC	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 11	No	0	0	0	-
09/0901	SC	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 11	No	0	0	0	-
09/0902		ES	VISIT 1	Yes	7	-	-	-
09/0903	ND plus	ES/SAF	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF	VISIT 3A	No	0	0	0	-
09/0904	ND basic	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	No	0	0	0	-
09/0905	ND plus	ES/SAF/FAS	VISIT 1	Yes	6	-	-	-
	ND plus	ES/SAF/FAS	VISIT 3A	Yes	10	-	-	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
09/0905	ND plus	ES/SAF/FAS	VISIT 4	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 5	Yes	5	-	-	-
	ND plus	ES/SAF/FAS	VISIT 6	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 7	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 8	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 9	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 10	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 11	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	10	-	-	-
09/0906		ES	VISIT 1	No	0	0	0	-
09/0907	SC	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 10	No	0	0	0	-
09/0908	ND basic	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	No	0	0	0	-
09/0909	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
09/0909	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
09/0910	ND plus	ES/SAF	VISIT 1	No	0	0	0	-
09/0911	ND plus	ES/SAF/FAS	VISIT 1	Yes	8	-	-	-
	ND plus	ES/SAF/FAS	VISIT 3A	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 4	Yes	8	-	-	-
	ND plus	ES/SAF/FAS	VISIT 5	Yes	8	-	-	-
	ND plus	ES/SAF/FAS	VISIT 6	Yes	8	-	-	-
	ND plus	ES/SAF/FAS	VISIT 7	Yes	8	-	-	-
	ND plus	ES/SAF/FAS	VISIT 8	Yes	8	-	-	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	-	-	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	-	-	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	-	-	-
09/0912	ND plus	ES/SAF/FAS	VISIT 1	Yes	15	-	-	-
	ND plus	ES/SAF/FAS	VISIT 3A	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 4	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 5	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 6	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 7	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 8	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 9	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 10	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 11	Yes	10	-	-	-
09/0913	ND basic	ES/SAF/FAS	VISIT 1	Yes	8	-	-	-
	ND basic	ES/SAF/FAS	VISIT 3A	Yes	6	-	-	-
	ND basic	ES/SAF/FAS	VISIT 4	Yes	6	-	-	-
	ND basic	ES/SAF/FAS	VISIT 5	Yes	6	-	-	-
	ND basic	ES/SAF/FAS	VISIT 6	Yes	6	-	-	-
	ND basic	ES/SAF/FAS	VISIT 7	Yes	6	-	-	-
	ND basic	ES/SAF/FAS	VISIT 8	Yes	6	-	-	-
	ND basic	ES/SAF/FAS	VISIT 9	Yes	6	-	-	-
	ND basic	ES/SAF/FAS	VISIT 10	Yes	6	-	-	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
09/0913	ND basic	ES/SAF/FAS	VISIT 11	Yes	6	-	-	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	Yes	8	-	-	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	Yes	6	-	-	-
09/0914	SC	ES/SAF/FAS	VISIT 1	Yes	8	-	-	-
	SC	ES/SAF/FAS	VISIT 4	Yes	8	-	-	-
	SC	ES/SAF/FAS	VISIT 5	Yes	4	-	-	-
	SC	ES/SAF/FAS	VISIT 6	Yes	4	-	-	-
	SC	ES/SAF/FAS	VISIT 7	Yes	4	-	-	-
	SC	ES/SAF/FAS	VISIT 8	Yes	4	-	-	-
	SC	ES/SAF/FAS	VISIT 9	Yes	4	-	-	-
	SC	ES/SAF/FAS	VISIT 10	Yes	4	-	-	-
	SC	ES/SAF/FAS	VISIT 11	Yes	4	-	-	-
09/0915	ND basic	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
09/0916	SC	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 11	No	0	0	0	-
10/1001		ES	VISIT 1	Yes	8	-	-	-
11/1101	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
11/1101	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	-	-	-	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	No	-	-	-	-
11/1102	ND basic	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	Yes	5	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	No	0	0	0	-
11/1103	SC	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	SC	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	SC	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
11/1104	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
11/1104	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
12/1201	ND plus	ES/SAF/FAS	VISIT 1	Yes	12	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	Yes	12	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 5	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 6	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 7	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 8	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 9	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 10	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	VISIT 11	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	12	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	10	-	-	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	10	-	-	-
12/1202		ES	VISIT 1	No	0	0	0	-
13/1301	ND plus	ES/SAF/FAS	VISIT 1	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 5	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	Yes	20	0	0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	Yes	20	0	0	-
13/1302	ND plus	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 4	No	0	0	0	-

Listing 16.2.1.3: Tobacco use - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Visit	Tobacco Use?	Number of cigarettes /day	Number of cigars/day	Number of pipes/day	Number of others/day
13/1302	ND plus	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND plus	ES/SAF/FAS	VISIT 11	No	0	0	0	-
13/1303	SC	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	SC	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	SC	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	SC	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
13/1304	ND basic	ES/SAF/FAS	VISIT 1	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 3A	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 4	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 5	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 6	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 7	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 8	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 9	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 10	No	0	0	0	-
	ND basic	ES/SAF/FAS	VISIT 11	No	0	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
	ND basic	ES/SAF/FAS	UNSCHEDULED	No	0	0	0	-
13/1305	ND plus	ES/SAF	VISIT 1	No	0	0	0	-

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
01-0103	NDisc basic	ES/SAF/FAS	Visit 1	Working fulltime				
			Baseline (Visit 2a)					7
			Visit 3a					89
			Visit 3l					21
			Visit 4					16
			Visit 5					56
			Visit 6					92
			Visit 7					174
			Visit 8					00
			Visit 9					00
			Visit 10					21
			Visit 11					00
01-0104	NDisc basic	ES/SAF/FAS	Visit 1	Working fulltime				
			Baseline (Visit 2a)					
			Visit 3a					41
			Visit 3l					12
			Visit 4					00
			Visit 5					
			Visit 6					00
			Visit 7					00
			Visit 8		Yes	2014-09-01	Not employed (e.g. homemaker, student)	
			Visit 9		Yes	2015-08-01	Working fulltime	00
			Visit 10					00
			Visit 11					03
01-0106	NDisc plus	ES/SAF/FAS	Visit 1	Working part-time				
			Baseline (Visit 2a)					103
			Visit 3a					82
			Visit 3l					23
			Visit 4					21
			Visit 5					18
			Visit 6					00
			Visit 7					00
			Visit 8					00
			Visit 9					00
			Visit 10					03
			Visit 11					00

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
01-0107	NDisc plus	ES/SAF/FAS	Visit 1	Working fulltime				
			Baseline (Visit 2a)					05
			Visit 3a					69
			Visit 3l					09
			Visit 4					00
			Visit 5					00
			Visit 6					00
			Visit 7					00
			Visit 8					00
			Visit 9					05
			Visit 10					00
			Visit 11					00
01-0108	NDisc plus	ES/SAF/FAS	Visit 1	Working fulltime				
			Baseline (Visit 2a)					00
			Visit 3a					42
			Visit 3l					04
			Visit 4					00
			Visit 5					00
			Visit 6					02
			Visit 7					00
			Visit 8					00
			Visit 9					05
			Visit 10					00
			Visit 11					05
01-0110	NDisc basic	ES/SAF/FAS	Visit 1	Working part-time				
			Baseline (Visit 2a)					4
			Visit 3a					87
			Visit 3l					23
			Visit 4					21
			Visit 5					39
			Visit 6					00
			Visit 7					00
			Visit 8					21
			Visit 9					00
			Visit 10					00
			Visit 11					00
01-0111	NDisc plus	ES/SAF/FAS	Visit 1	Working fulltime				

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
01-0111	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)					0
			Visit 3a					76
			Visit 3l					22
			Visit 4					23
			Visit 5					02
			Visit 6					00
			Visit 7					00
			Visit 8					02
			Visit 9					00
			Visit 10					03
			Visit 11					10
01-0112	NDisc basic	ES/SAF	Visit 1	Working fulltime				
			Baseline (Visit 2a)					02
			Unscheduled		Yes	2013-03-26	Unemployed	7
			Visit 11					94
01-0113	NDisc basic	ES/SAF/FAS	Visit 1	Working fulltime				
			Baseline (Visit 2a)					02
			Visit 3a					53
			Visit 3l					05
			Visit 4					00
			Visit 5					00
			Visit 6					00
			Unscheduled					00
			Visit 7					00
			Unscheduled					00
			Unscheduled					30
			Unscheduled					29
			Visit 8					79
			Visit 9					05
01-0114	NDisc basic	ES/SAF/FAS	Visit 10					00
			Visit 11					00
			Visit 1	Not employed (e.g. homemaker, student)				
			Baseline (Visit 2a)					00
			Visit 3a					NA
			Visit 3l					NA
			Visit 4					NA

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
01-0114	NDisc basic	ES/SAF/FAS	Visit 5					00
			Visit 6					00
			Visit 7					00
			Visit 8		Yes	2015-06-01	Working part-time	00
			Visit 9					00
			Visit 10					05
			Visit 11					10
01-0115	NDisc plus	ES/SAF/FAS	Visit 1	Working fulltime				
			Baseline (Visit 2a)					00
			Visit 3a					96
			Visit 3l					21
			Visit 4					22
			Visit 5					31
			Visit 6					00
			Visit 7					00
			Visit 8					00
			Visit 9					00
			Visit 10					00
			Visit 11					00
01-0116	NDisc basic	ES/SAF	Visit 1	Working part-time				
			Baseline (Visit 2a)					00
01-0118	NDisc plus	ES/SAF/FAS	Visit 1	Working fulltime				
			Baseline (Visit 2a)					01
			Visit 3a					90
			Visit 3l					23
			Visit 4					21
			Visit 5					48
			Visit 6					77
			Unscheduled					42
			Unscheduled					42
			Unscheduled					42
			Unscheduled					29
			Visit 7					14
			Unscheduled					14
			Visit 8		Yes	2015-03-01	Unemployed	00
			Unscheduled					00
			Visit 9					00

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
01-0118	NDisc plus	ES/SAF/FAS	Visit 10 Unscheduled Unscheduled Visit 11					00 UN UNK 30
01-0119	NDisc basic	ES/SAF/FAS	Visit 1 Baseline (Visit 2a) Visit 3a Visit 3l Visit 4 Visit 5 Visit 6 Unscheduled Visit 7 Visit 8 Visit 9 Visit 10 Visit 11	Working fulltime				02 84 23 13 56 06 00 05 43 10 40 50
					Yes	2018-09-29	Unemployed	
01-0121	NDisc plus	ES/SAF/FAS	Visit 1 Baseline (Visit 2a) Visit 3a Visit 3l Visit 4 Visit 5 Visit 6 Visit 7 Visit 8 Visit 9	Working fulltime				25 90 20 13 20 00 05 05 00
01-0122	NDisc plus	ES/SAF/FAS	Visit 1 Baseline (Visit 2a) Visit 3a Visit 3l Visit 4 Visit 5 Visit 6 Visit 7 Visit 8 Unscheduled	Working fulltime				00 81 21 20 05 00 14 13 08

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
01-0122	NDisc plus	ES/SAF/FAS	Visit 9 Visit 10 Visit 11					00 00 05
01-0123	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a) Visit 3a Visit 4 Visit 5 Visit 6 Visit 7 Visit 8 Unscheduled Unscheduled Visit 9 Unscheduled Visit 10	Working fulltime	Yes	2015-07-01	Unemployed	93 40 18 00 00 00 00 00 00 00 00 155
01-0124	NDisc plus	ES/SAF	Baseline (Visit 2a)	Working fulltime				34
01-0125	SC	ES/SAF/FAS	Baseline (Visit 2a) Visit 4 Visit 5 Visit 6 Visit 7 Visit 8 Visit 9 Unscheduled Visit 10 Visit 11	Working fulltime				00 30 00 02 00 00 00 00 00 00
01-0126	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a) Visit 3a Visit 4 Unscheduled Visit 5 Visit 6 Visit 7 Visit 8 Visit 9 Visit 10	Working part-time				00 54 21 03 29 00 00 00 02 09

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
01-0126	NDisc basic	ES/SAF/FAS	Visit 11					06
01-0127	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				
			Visit 3a					80
			Visit 4					09
			Visit 5					00
			Visit 6					00
			Visit 7					00
			Visit 8					00
			Visit 9					00
			Unscheduled					00
			Visit 10					00
			Visit 11					00
01-0128	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Unemployed				
			Visit 3a					75
			Visit 4					23
			Visit 5					00
			Visit 6					00
			Visit 7					05
			Visit 8					00
			Visit 9					00
			Visit 10					00
			Unscheduled					
			Visit 11					00
01-0129	SC	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				
			Visit 4					42
			Visit 5					31
			Visit 6					23
			Visit 7					03
			Visit 8					00
			Visit 9					01
			Visit 10					00
			Unscheduled					UNK
			Unscheduled					UNK
			Visit 11					00
01-0130	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				17
			Visit 3a					24

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
01-0130	NDisc basic	ES/SAF/FAS	Visit 4					02
			Visit 5					
			Visit 6					00
			Visit 7					00
			Visit 8					00
			Visit 9					00
			Visit 10					00
			Visit 11					00
01-0131	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				06
			Visit 3a					80
			Visit 4					28
			Visit 5					00
			Visit 6					00
			Visit 7					23
			Visit 8					02
			Visit 9					00
			Visit 10					03
			Visit 11					00
01-0132	SC	ES/SAF/FAS	Baseline (Visit 2a)	Unemployed				00
			Visit 4					42
			Visit 5					21
			Visit 6					0
			Visit 7					00
			Visit 8					00
			Visit 9					01
			Visit 10		Yes	2018-09-03	Working fulltime	05
			Visit 11					00
01-0133	NDisc plus	ES/SAF	Baseline (Visit 2a)	Working part-time				50
			Unscheduled					13
01-0134	NDisc basic	ES/SAF	Baseline (Visit 2a)	Working fulltime				22
			Unscheduled					29
01-0135	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				54
			Visit 3a					83
			Visit 4					34
			Visit 5					00

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
01-0135	NDisc plus	ES/SAF/FAS	Visit 6					00
			Visit 7					00
			Visit 8					00
			Visit 9					00
			Visit 10		Yes	2019-03-01	Working part-time	10
			Visit 11					00
01-0136	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				65
			Visit 3a					99
			Visit 4					02
			Visit 5					00
			Unscheduled					00
			Visit 6					00
			Visit 7					14
			Visit 8					00
			Visit 9					45
			Visit 10					
			Visit 11		Yes	2020-03	Unemployed	00
01-0137	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working part-time				02
			Visit 3a					78
			Visit 4					05
			Visit 5					00
			Visit 6					20
			Visit 7					00
			Visit 8					00
			Visit 9		Yes	2017-07-07	Not employed (e.g. homemaker, student)	00
			Visit 10					
			Visit 11					00
01-0138	SC	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				04
			Visit 4					30
			Visit 5					00
			Visit 6					00
			Visit 7					00
			Visit 8					00
			Visit 9					00
			Visit 10					04
			Visit 11					00

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
01-0139	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Not employed (e.g. homemaker, student)				00
			Visit 3a					00
			Visit 4					00
			Visit 5					00
			Visit 6					00
			Visit 7					00
			Unscheduled					03
			Visit 8					UNK
			Visit 9					00
			Visit 10					
01-0140	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				08
			Visit 3a					90
			Visit 4					42
			Visit 5					40
			Visit 6					00
			Visit 7					00
			Visit 8					03
			Visit 9					03
			Visit 10					00
			Visit 11					00
01-0141	SC	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				26
			Visit 4					47
			Visit 5					48
			Visit 6					00
			Visit 7					00
			Visit 8					10
			Visit 9					
			Visit 10					00
			Visit 11					00
			Unscheduled		Yes	2020-03	Not employed (e.g. homemaker, student)	00
01-0142	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working part-time				00
			Visit 3a					00
			Visit 4					00
			Visit 5					00
			Visit 6					00

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
01-0142	NDisc plus	ES/SAF/FAS	Visit 7					00
			Visit 8					00
			Visit 9					09
			Visit 10					00
			Visit 11					00
01-0143	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				77
			Visit 3a					48
			Visit 4					03
			Visit 5					00
			Visit 6					00
			Visit 7					00
			Visit 8					00
			Visit 9					05
			Visit 10					05
			Visit 11					00
01-0144	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				44
			Visit 3a					00
			Visit 4					00
			Visit 5					00
			Visit 6					00
			Visit 7					00
			Visit 8					00
			Visit 9					10
			Unscheduled					
			Unscheduled					
			Visit 10					00
			Visit 11					00
01-0145	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working part-time				00
			Unscheduled					50
			Visit 3a					21
			Visit 4					25
			Visit 5					00
			Visit 6					00
			Visit 7					00
			Visit 8					00
			Visit 9		Yes	2017-10-02	Not employed (e.g. homemaker, student)	00

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
01-0145	NDisc plus	ES/SAF/FAS	Visit 10 Visit 11					18 00
01-0146	SC	ES/SAF/FAS	Baseline (Visit 2a) Visit 4 Visit 5 Visit 6 Visit 7 Visit 8 Visit 9 Visit 10 Visit 11	Working fulltime				00 42 39 00 00 00 00 04 00
01-0147	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a) Visit 3a Visit 4 Visit 5 Visit 6 Visit 7 Visit 8 Visit 9 Visit 10 Visit 11	Working part-time				83 89 13 00 00 00 00 00 00 00
01-0148	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a) Visit 3a Visit 4 Visit 5 Visit 6 Visit 7 Visit 8 Visit 9 Unscheduled Visit 10 Visit 11	Working fulltime				01 39 00 00 00 00 05 05 UNK 03 00
01-0149	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a) Visit 3a Visit 4 Visit 5	Working fulltime				07 43 00 00

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
01-0149	NDisc plus	ES/SAF/FAS	Visit 6					00
			Visit 7					05
			Visit 8					05
			Visit 9					02
			Visit 10					00
			Visit 11					00
01-0151	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				44
			Visit 3a					42
			Visit 4					05
			Visit 5					00
			Visit 6					00
			Visit 7					03
			Visit 8					05
			Visit 9					07
			Visit 10					05
			Visit 11					07
01-0152	SC	ES/SAF/FAS	Baseline (Visit 2a)	Working part-time				00
			Visit 4					49
			Visit 5					34
			Visit 6					00
			Visit 7					00
			Visit 8					00
			Visit 9					00
			Visit 10					00
			Visit 11		Yes	2021-04	Working part-time	00
01-0153	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				05
			Visit 3a					77
			Unscheduled					15
			Visit 4					43
			Visit 5					49
			Visit 6					84
			Visit 7					00
			Unscheduled					07
			Visit 8					68
			Unscheduled					UNK
			Visit 9		Yes	2019-01	Unemployed	40
			Visit 10		Yes	2019-05-01	Working fulltime	25

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
01-0153	NDisc basic	ES/SAF/FAS	Visit 11		Yes	2020-07-01	Not employed (e.g. homemaker, student)	05
02-0201	NDisc plus	ES/SAF/FAS	Visit 1 Baseline (Visit 2a) Visit 3a Visit 3l Visit 4 Visit 5 Visit 6 Visit 7 Visit 8 Unscheduled Visit 9 Visit 10 Visit 11	Working fulltime	Yes Yes	2013-04-12 2013-05-21	Working part-time Working fulltime	29 00 00 00 0 65 00
02-0202	NDisc basic	ES/SAF	Visit 1 Baseline (Visit 2a)	Working fulltime				06
02-0203	NDisc basic	ES/SAF/FAS	Visit 1 Baseline (Visit 2a) Visit 3a Visit 3l Visit 4 Visit 5 Visit 6 Unscheduled Unscheduled Visit 7 Visit 8 Unscheduled Visit 9 Unscheduled Unscheduled Visit 10 Visit 11	Working fulltime	Yes	2014-02-24	Working part-time	14 43 0 00 00 02 78 00 00 00 00 00
02-0204	NDisc basic	ES/SAF	Visit 1 Baseline (Visit 2a)	Working fulltime				07

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
02-0205	NDisc basic	ES/SAF/FAS	Visit 1	Working fulltime				
			Baseline (Visit 2a)					28
			Visit 3a					71
			Visit 3l					00
			Visit 4					00
			Visit 5					
			Visit 6					
			Visit 7					
			Visit 8					05
			Visit 9					
			Visit 10					00
			Visit 11					00
02-0206	NDisc plus	ES/SAF/FAS	Visit 10	Working fulltime				
			Visit 1					
			Baseline (Visit 2a)					17
			Visit 3a					95
			Visit 3l					22
			Visit 4					22
			Visit 5					
			Visit 6					
			Visit 7					
			Visit 9					
			Visit 11					UNK
02-0208	NDisc plus	ES/SAF/FAS	Visit 1	Unemployed				
			Baseline (Visit 2a)					
			Visit 3a					89
			Unscheduled					06
			Visit 3l					21
			Visit 4					23
			Visit 5					
			Unscheduled					
			Visit 6					
			Visit 7		Yes	2014-09-20	Working fulltime	00
			Unscheduled					1
			Unscheduled					UNK
			Visit 8					
			Visit 9					00
			Visit 10					

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
02-0208	NDisc plus	ES/SAF/FAS	Visit 11					00
02-0209	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				26
			Visit 3a					00
			Visit 4					
			Visit 5					
			Visit 6					
			Unscheduled					
			Visit 7					
			Visit 8					00
			Visit 9					
			Visit 10					
			Visit 11					
02-0211	NDisc basic	ES/SAF	Baseline (Visit 2a)	Working fulltime		2014-12-08		02
			Visit 3a					
02-0212	SC	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime		2014-12-08		05
			Visit 4					29
			Visit 5		Yes	2015-03-13	Working fulltime	00
			Visit 6					
			Visit 7					
			Visit 8					00
			Visit 9					
			Visit 10					UNK
			Visit 11					UNK
02-0213	NDisc plus	ES/SAF	Baseline (Visit 2a)	Working fulltime		2014-12-02		15
02-0214	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Unemployed				
			Visit 3a					
			Visit 4					
			Visit 6		Yes	2015-10	Working fulltime	
			Visit 7		Yes	2016-05-26	Working part-time	30
			Visit 9					
			Visit 11		Yes	2018	Working fulltime	20
02-0216	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				00
			Visit 3a					
			Unscheduled					06

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
02-0216	NDisc plus	ES/SAF/FAS	Unscheduled Visit 4 Visit 5					09
02-0217	SC	ES/SAF/FAS	Baseline (Visit 2a) Visit 4 Visit 5 Visit 6 Visit 7 Visit 8 Visit 9 Visit 10 Visit 11	Working fulltime				180
					Yes	2016-05-02	Working fulltime	00 21
02-0218	NDisc basic	ES/SAF	Baseline (Visit 2a)	Working fulltime				
02-0219	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a) Visit 3a Visit 4 Visit 5 Visit 6 Visit 7 Visit 8 Visit 9 Visit 10 Visit 11	Working fulltime	Yes	2015-05-19 2015-08-03	Working fulltime	16
						2016-10		00 UNK ND 0
02-0220	SC	ES/SAF/FAS	Baseline (Visit 2a) Visit 4 Visit 5 Visit 6 Visit 7 Visit 8 Visit 9 Visit 10 Visit 11	Working part-time		2015-02		180
					Yes	2015-11-01	Working fulltime	33
					Yes	2015-12-01	Unemployed	
					Yes	2017-06-12	Working part-time	00 00 05 UNK
02-0221	NDisc plus	ES/SAF	Baseline (Visit 2a) Visit 3a	Working fulltime	Yes	2015-08-17	Working fulltime	10

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
02-0222	NDisc plus	ES/SAF	Baseline (Visit 2a)	Working fulltime	Yes	2015-07-27	Working fulltime	
02-0223	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				00
			Visit 3a					
			Visit 4		Yes	2016-04-04	Working part-time	UNK
			Visit 5					
			Visit 6					10
			Visit 7					00
			Visit 8					33
			Visit 9					
			Visit 10					10
			Visit 11		Yes	2021-02-01	Unemployed	
02-0224	NDisc plus	ES/SAF	Baseline (Visit 2a)	Working fulltime				
04-0401	SC	ES/SAF/FAS	Baseline (Visit 2a)	Not employed (e.g. homemaker, student)				
			Visit 4					
			Visit 5					
			Visit 6					
			Visit 7					
			Visit 8					
			Visit 9		Yes	2018-07-25	Working fulltime	00
			Visit 10					
			Visit 11					0
06-0602	NDisc plus	ES/SAF/FAS	Visit 1	Working fulltime				
			Baseline (Visit 2a)					07
			Visit 3a					28
			Visit 4					00
			Visit 5					
			Visit 6					00
			Visit 7					
			Visit 8					180
06-0604	NDisc basic	ES/SAF	Baseline (Visit 2a)	Working fulltime				
06-0605	NDisc plus	ES/SAF	Baseline (Visit 2a)	Working fulltime				
06-0606	SC	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				229

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
06-0606	SC	ES/SAF/FAS	Visit 4					36
			Visit 5					22
			Visit 6		Yes	2015-04-01	Working part-time	19
			Visit 7		Yes	2015-10-28	Unemployed	32
			Visit 8		Yes	2015-12-20	Working fulltime	05
			Visit 9					20
			Visit 10					25
			Visit 11					21
06-0607	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				15
			Visit 3a					
			Visit 4		Yes	2015-04-19	Unemployed	06
			Visit 5		Yes	2015-06	Working fulltime	02
			Visit 6					00
			Visit 7					00
			Visit 8					00
			Visit 9					17
			Unscheduled					02
			Visit 10					26
			Visit 11					00
06-0608	SC	ES/SAF	Baseline (Visit 2a)	Working fulltime				04
06-0609	NDisc basic	ES/SAF	Baseline (Visit 2a)	Not employed (e.g. homemaker, student)				
06-0610	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				93
			Visit 3a					75
			Visit 4					35
			Visit 5					35
			Unscheduled					26
			Visit 6					41
			Visit 7		Yes	2016-06-13	Working part-time	54
			Visit 8		Yes	2017-07-31	Unemployed	UNK
			Visit 11		Yes	2019-06	Working part-time	00
06-0612	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				00
			Visit 3a					39
			Visit 4					03
			Visit 5					00

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
06-0612	NDisc plus	ES/SAF/FAS	Visit 6					01
			Unscheduled					02
			Visit 7					05
			Visit 8					30
			Visit 9					07
			Visit 10					01
			Unscheduled					00
			Visit 11		Yes	2019-12-01	Retired	10
06-0613	SC	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				25
			Visit 4					33
			Visit 5					00
			Visit 6					00
			Visit 7					
			Visit 8					14
			Visit 9					10
			Visit 10					00
			Visit 11					14
06-0614	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				02
			Visit 3a					94
			Visit 4					33
			Visit 5					27
			Unscheduled					09
			Unscheduled					13
			Visit 6					35
			Unscheduled					64
			Unscheduled					07
			Visit 7					68
			Visit 8					350
			Unscheduled					13
			Visit 9		Yes	2017-12	Unemployed	UNK
			Visit 10		Yes	2019-11-11	Working fulltime	
			Visit 11					00
06-0615	NDisc basic	ES/SAF	Baseline (Visit 2a)	Working fulltime				10
06-0617	NDisc plus	ES/SAF	Baseline (Visit 2a)	Working fulltime				08
			Visit 3a					52

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
06-0619	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				06
			Visit 3a					22
			Visit 4					00
			Visit 5					00
			Visit 6					00
			Visit 7					14
			Visit 8					143
			Visit 9					363
			Visit 10					42
			Visit 11					15
06-0620	SC	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				137
			Visit 4					29
			Visit 5					
			Visit 6					00
			Visit 7					00
			Visit 8					03
			Visit 9					00
			Visit 10					02
			Visit 11					10
07-0701	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Not employed (e.g. homemaker, student)				
			Visit 3a					
			Visit 4					
			Visit 5					
			Visit 6					
			Visit 7					00
			Visit 8					
			Visit 9					
			Visit 10					10
			Visit 11		Yes	2020-01-01	Working fulltime	00
07-0702	SC	ES/SAF/FAS	Visit 11					
			Baseline (Visit 2a)	Working fulltime				11
			Visit 4					02
			Visit 5					
			Visit 6		Yes	2015-06-01	Working part-time	00
			Visit 8		Yes	2017-08-01	Unemployed	
			Visit 10					00

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
07-0703	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				
			Visit 3a					
			Visit 4					
			Visit 5		Yes	2015-08-03	Working fulltime	00
			Visit 6		Yes	2015-09-01	Not employed (e.g. homemaker, student)	
			Visit 7					
			Visit 8		Yes	2016-08-22	Working part-time	00
			Visit 9					
			Visit 10					00
			Visit 11		Yes		Working fulltime	00
07-0704	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				
			Visit 3a					20
			Visit 4					00
			Visit 5					00
			Visit 6					00
			Visit 7					00
			Visit 8					00
			Visit 9					00
			Visit 10					05
			Visit 11					00
07-0706	SC	ES/SAF/FAS	Baseline (Visit 2a)	Working part-time				17
			Visit 4		Yes	2015-12-31	Unemployed	31
08-0801	SC	ES/SAF/FAS	Baseline (Visit 2a)	Working part-time				31
			Visit 4					42
			Visit 5					52
			Visit 6					
08-0802	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				70
			Visit 3a					80
			Visit 4					07
			Visit 5					00
			Visit 6					
			Visit 7					00
			Visit 8					
			Visit 9					37
			Visit 10					10

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
08-0802	NDisc plus	ES/SAF/FAS	Visit 11					0
08-0803	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				42
			Visit 3a					36
			Visit 4					
			Visit 5					
08-0804	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				8
			Visit 3a					
			Visit 4					00
			Visit 5					00
			Visit 6					00
			Visit 7					
			Visit 8					00
			Visit 9					00
			Visit 10					00
			Visit 11					00
08-0805	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Working part-time				57
			Visit 3a					39
			Visit 4					0
			Visit 5					0
			Visit 6					00
			Unscheduled					
			Unscheduled					00
			Visit 7					03
			Visit 8					00
			Visit 9					20
			Visit 10		Yes	2019-05-01	Working part-time	06
			Visit 11					14
08-0806	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working part-time				15
			Visit 3a					82
			Visit 4					17
			Visit 5					00
			Visit 6					01
			Visit 7					
			Visit 8					128
			Visit 9					150
			Visit 10					00

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
08-0806	NDisc plus	ES/SAF/FAS	Visit 11					0
08-0807	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working part-time				9
			Visit 3a					75
			Visit 4					20
			Unscheduled					08
			Visit 5					00
			Visit 6					
			Visit 7					
			Visit 8					00
08-0808	SC	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				01
			Visit 4					35
			Visit 5					
			Visit 6		Yes	2016-04-01	Retired	00
			Visit 7					
			Visit 8					
			Visit 9					
			Visit 10					
			Visit 11					00
09-0901	SC	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				26
			Visit 4		Yes	2014-12-15	Working fulltime	00
			Visit 5					00
			Visit 6					00
			Visit 7					00
			Visit 8					00
			Visit 9					00
			Visit 10					00
			Visit 11					00
09-0903	NDisc plus	ES/SAF	Baseline (Visit 2a)	Working fulltime		2014-10-14		30
			Visit 3a					82
09-0904	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				05
			Visit 3a					81
			Visit 4					26
			Visit 5					00
			Visit 6					00
			Visit 7					25

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
09-0904	NDisc basic	ES/SAF/FAS	Visit 8 Visit 9 Visit 10 Visit 11					00 00 00 09
09-0905	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a) Visit 3a Visit 4 Visit 5 Visit 6 Visit 7 Visit 8 Visit 9 Unscheduled Unscheduled Unscheduled Visit 10 Visit 11	Working fulltime				05 69 32 30 42 00 00 00 16 147 21 103 96
09-0907	SC	ES/SAF/FAS	Baseline (Visit 2a) Visit 4 Visit 5 Visit 6 Visit 7 Visit 8 Visit 9 Visit 10 Visit 11	Working fulltime				45 32 00 00 00 10 05 12 00
09-0908	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a) Visit 3a Visit 4 Visit 5 Visit 6 Visit 7 Visit 8 Visit 9 Visit 10 Visit 11	Working fulltime				02 34 00 00 00 00 00 00 00 00

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
09-0909	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working part-time				42
			Visit 3a					63
			Unscheduled					06
			Visit 4					07
			Visit 5					00
			Visit 6					00
			Visit 7					00
			Visit 8					00
			Visit 9					00
			Visit 10					00
			Visit 11					03
09-0910	NDisc plus	ES/SAF	Baseline (Visit 2a)	Working fulltime				11
09-0911	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working part-time	Yes	2015-05-31	Unemployed	179
			Visit 3a					65
			Visit 4					26
			Visit 5					35
			Visit 6					00
			Visit 7					00
			Visit 8					31
			Visit 9					00
			Visit 10					00
			Visit 11					14
09-0912	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				07
			Visit 3a					49
			Visit 4					00
			Visit 5					00
			Visit 6					00
			Visit 7					00
			Visit 8					00
			Visit 9					14
			Visit 10					00
			Visit 11					00
09-0913	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Working part-time				10
			Unscheduled					3
			Visit 3a					63
			Visit 4					08

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
09-0913	NDisc basic	ES/SAF/FAS	Visit 5					00
			Visit 6					00
			Unscheduled					00
			Visit 7					00
			Visit 8					00
			Visit 9					UNK
			Visit 10					00
			Visit 11					00
09-0914	SC	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				22
			Visit 4					28
			Visit 5		Yes	2016-02-29	Unemployed	40
			Visit 6					00
			Visit 7					00
			Visit 8		Yes	2017-08-01	Working fulltime	00
			Visit 9					00
			Visit 10					00
09-0915	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				01
			Visit 3a					27
			Visit 4					00
			Visit 5					00
			Visit 6					00
			Unscheduled					00
			Visit 7					
			Visit 8					
09-0916	SC	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				31
			Visit 4					32
			Visit 5					14
			Visit 6					00
			Visit 7					37
			Visit 8					14
			Visit 9					00
			Visit 10					00

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
09-0916	SC	ES/SAF/FAS	Visit 11		Yes	2020-12-01	Working part-time	00
11-1101	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				09
			Visit 3a					50
			Visit 4					11
			Visit 5					
			Visit 6					02
			Visit 7					03
			Visit 8					07
			Unscheduled					12
			Visit 9					181
			Visit 10					352
			Unscheduled					71
			Unscheduled					22
			Visit 11		Yes	2019-05-01	Retired	UNK
11-1102	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Working part-time				10
			Visit 3a					15
			Visit 4					
			Visit 5					00
			Visit 6					
			Visit 7					00
			Visit 8					00
			Visit 9					00
			Visit 10		Yes	2018-09	Working fulltime	00
			Visit 11					00
11-1103	SC	ES/SAF/FAS	Baseline (Visit 2a)	Unemployed				
			Visit 4					25
			Visit 5					
			Visit 6					
			Visit 7					00
			Visit 8					00
			Unscheduled					
			Unscheduled					
			Visit 9					00
			Visit 10					00
			Visit 11					410
11-1104	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Working fulltime				09

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
11-1104	NDisc plus	ES/SAF/FAS	Visit 3a					35
			Visit 4					00
			Visit 5					00
			Visit 6					00
			Visit 7					00
			Visit 8					00
			Visit 9					00
			Visit 10					00
			Visit 11					00
			Baseline (Visit 2a) Working fulltime					
			Unscheduled					33
12-1201	NDisc plus	ES/SAF/FAS	Visit 3a					87
			Visit 4					38
			Visit 5		Yes	2016-02-08	Working fulltime	0
			Unscheduled					
			Visit 6					
			Unscheduled					
			Visit 7					
			Unscheduled					
			Visit 8		Yes	2017-01-01	Retired	0
			Unscheduled					0
			Visit 9					
13-1301	NDisc plus	ES/SAF/FAS	Visit 10					0
			Visit 11					
			Baseline (Visit 2a) Working fulltime					14
			Unscheduled					00
			Visit 3a					61
			Visit 4					30
			Visit 5					
			Visit 6		Yes	2015-12-06	Working fulltime	00
			Visit 7					00
			Visit 8					00
			Visit 9		Yes	2017-11	Working fulltime	UNK
13-1302	NDisc plus	ES/SAF/FAS	Visit 10		Yes	2020-03-01	Working fulltime	10
			Visit 11					
13-1302	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a) Working fulltime		Yes	2015-05-05	Not employed (e.g. homemaker, student)	07

Listing 16.2.1.4: Work status - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Employment during healthy status	Change of employment status?	Date of change of employment status	Employment status	Days off work due to illness
13-1302	NDisc plus	ES/SAF/FAS	Visit 3a		Yes	2015-07-15	Working part-time	10
			Visit 4		Yes	2015-08-15	Working fulltime	00
			Visit 5					00
			Visit 6					
			Visit 7					00
			Visit 8					05
			Visit 9					05
			Visit 10					UNK
			Visit 11					00
13-1303	SC	ES/SAF/FAS	Baseline (Visit 2a)	Working part-time				10
			Visit 4					63
			Visit 5					
			Visit 6					00
			Visit 7					00
			Visit 8					00
			Unscheduled					00
			Visit 9					UNK
			Visit 10					UNK
			Visit 11					00
			Unscheduled					00
13-1304	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Working part-time				21
			Unscheduled					48
			Visit 3a		Yes	2015-08-31	Working part-time	77
			Visit 4					00
			Unscheduled					00
			Visit 5					00
			Visit 6					
			Unscheduled					00
			Visit 7					
			Visit 8					03
			Unscheduled		Yes	2018-04-01	Working part-time	00
			Visit 9					00
			Visit 10					UNK
			Visit 11					04
13-1305	NDisc plus	ES/SAF	Baseline (Visit 2a)	Working part-time				03

Listing 16.2.1.5: Anamnesis at Screening - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Type of degenerated lumbar disc	Location of herniated disc	Location of adjacent disc	Start Date of current complaints	Time since start of complaints (days)
01/0102		ES	HD	L5 and S1 Left		- -	-
01/0103	ND basic	ES/SAF/FAS	HD	L4 and L5 Right		- -	-
01/0104	ND basic	ES/SAF/FAS	ADD	L5 and S1 Right		- -	-
01/0105		ES	HD	L5 and S1 Left		- -	-
01/0106	ND plus	ES/SAF/FAS	HD	L5 and S1 Right		- -	-
01/0107	ND plus	ES/SAF/FAS	HD	L4 and L5 Right		- -	-
01/0108	ND plus	ES/SAF/FAS	HD	L5 and S1 Left		- -	-
01/0109		ES	HD	L4 and L5 Left		- -	-
01/0110	ND basic	ES/SAF/FAS	ADD	L5 and S1 Right	L4 and L5 Right	- -	-
01/0111	ND plus	ES/SAF/FAS	HD	L5 and S1 Left		- -	-
01/0112	ND basic	ES/SAF	HD	L5 and S1 Right		- -	-
01/0113	ND basic	ES/SAF/FAS	HD	L5 and S1 Left		- -	-
01/0114	ND basic	ES/SAF/FAS	HD	L4 and L5 Left		- -	-
01/0115	ND plus	ES/SAF/FAS	HD	L5 and S1 Left		- -	-
01/0116	ND basic	ES/SAF	ADD	L5 and S1 Right	L4 and L5 Right	- -	-
01/0117		ES	HD	L5 and S1 Right		- -	-
01/0118	ND plus	ES/SAF/FAS	HD	L5 and S1 Left		- -	-
01/0119	ND basic	ES/SAF/FAS	HD	L5 and S1 Left		- -	-
01/0120		ES	ADD	L5 and S1 Left	L4 and L5	- -	-

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

For computation of 'Time since start of complaints': missing day was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_anam.lst / l_anam.sas

Page 1 of 8

-continued on next page-

Listing 16.2.1.5: Anamnesis at Screening - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Type of degenerated lumbar disc	Location of herniated disc	Location of adjacent disc	Start Date of current complaints	Time since start of complaints (days)
01/0121	ND plus	ES/SAF/FAS	HD	L5 and S1 Right		- -	-
01/0122	ND plus	ES/SAF/FAS	HD	L5 and S1 Left		- -	-
01/0123	ND plus	ES/SAF/FAS	HD	L4 and L5 Right		2013-09	381
01/0124	ND plus	ES/SAF	HD	L5 and S1 Right		2014-05	190
01/0125	SC	ES/SAF/FAS	HD	L5 and S1 Left		2014-10-03	5
01/0126	ND basic	ES/SAF/FAS	HD	L4 and L5 Left		2014-10-03	6
01/0127	ND plus	ES/SAF/FAS	HD	L5 and S1 Right		2014-10-02	19
01/0128	ND plus	ES/SAF/FAS	ADD	L4 and L5 Right	L5 and S1 NA	2014-10-06	16
01/0129	SC	ES/SAF/FAS	HD	L4 and L5 Right		2014-10-27	3
01/0130	ND basic	ES/SAF/FAS	HD	L4 and L5 Left		2014-06-01	173
01/0131	ND plus	ES/SAF/FAS	HD	L4 and L5 Right		2014-07-01	154
01/0132	SC	ES/SAF/FAS	HD	L4 and L5 Left		2014-06-01	185
01/0133	ND plus	ES/SAF	HD	L4 and L5 Left		2014-04	260
01/0134	ND basic	ES/SAF	HD	L5 and S1 Left		2014-11-25	23
01/0135	ND plus	ES/SAF/FAS	HD	L5 and S1 Right		2014-11-12	65
01/0136	ND basic	ES/SAF/FAS	HD	L4 and L5 Right		2014-11	115
01/0137	ND plus	ES/SAF/FAS	HD	L4 and L5 Left		2015-02-05	22
01/0138	SC	ES/SAF/FAS	HD	L5 and S1 Right		2015-01-01	68
01/0139	ND plus	ES/SAF/FAS	HD	L5 and S1 Right		2015-01-01	69

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

For computation of 'Time since start of complaints': missing day was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_anam.lst / l_anam.sas

Page 2 of 8

-continued on next page-

Listing 16.2.1.5: Anamnesis at Screening - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Type of degenerated lumbar disc	Location of herniated disc	Location of adjacent disc	Start Date of current complaints	Time since start of complaints (days)
01/0140	ND basic	ES/SAF/FAS	HD	L5 and S1 Right		2015-03-16	58
01/0141	SC	ES/SAF/FAS	HD	L4 and L5 Right		2015-04	57
01/0142	ND plus	ES/SAF/FAS	HD	L5 and S1 Right		2015-05-05	23
01/0143	ND plus	ES/SAF/FAS	HD	L4 and L5 Left		2014-12	199
01/0144	ND basic	ES/SAF/FAS	HD	L5 and S1 Left		2015-05-10	46
01/0145	ND plus	ES/SAF/FAS	HD	L5 and S1 Right		2015-06-01	46
01/0146	SC	ES/SAF/FAS	HD	L5 and S1 Left		2015-01	197
01/0147	ND plus	ES/SAF/FAS	HD	L4 and L5 Left		2015-04	142
01/0148	ND plus	ES/SAF/FAS	HD	L5 and S1 Right		2015-07-11	104
01/0149	ND plus	ES/SAF/FAS	HD	L4 and L5 Left		2015-09-26	69
01/0150		ES	HD	L4 and L5 Left		2015-09-01	156
01/0151	ND basic	ES/SAF/FAS	ADD	L5 and S1 Right	L4 and L5 Right	2016-01-18	46
01/0152	SC	ES/SAF/FAS	HD	L5 and S1 Left		2015-11	124
01/0153	ND basic	ES/SAF/FAS	ADD	L5 and S1 Right	L4 and L5 Right	2016-03-07	15
02/0201	ND plus	ES/SAF/FAS	ADD	L4 and L5 Left	L5 and S1 UNK	- -	-
02/0202	ND basic	ES/SAF	HD	L5 and S1 Left		- -	-
02/0203	ND basic	ES/SAF/FAS	ADD	L4 and L5 Left	L3 and L4 Left	- -	-
02/0204	ND basic	ES/SAF	ADD	L5 and S1 Left	L4 and L5 UNK	- -	-
02/0205	ND basic	ES/SAF/FAS	HD	L5 and S1 Left		- -	-

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

For computation of 'Time since start of complaints': missing day was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_anam.lst / l_anam.sas

Page 3 of 8

-continued on next page-

Listing 16.2.1.5: Anamnesis at Screening - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Type of degenerated lumbar disc	Location of herniated disc	Location of adjacent disc	Start Date of current complaints	Time since start of complaints (days)
02/0206	ND plus	ES/SAF/FAS	HD	L4 and L5 Left		- -	-
02/0207		ES	HD	L5 and S1 Right		- -	-
02/0208	ND plus	ES/SAF/FAS	ADD	L5 and S1 Left	L4 and L5 Left/Right	- -	-
02/0209	ND plus	ES/SAF/FAS	HD	L4 and L5 Right		2014-08	84
02/0210		ES				- -	-
02/0211	ND basic	ES/SAF	HD	L5 and S1 Right		2014-01	345
02/0212	SC	ES/SAF/FAS	HD	L3 and L4 Left		2014-11	46
02/0213	ND plus	ES/SAF	HD	L5 and S1 Left		2014-05	232
02/0214	ND plus	ES/SAF/FAS	HD	L4 and L5 Right		2014-05	301
02/0215		ES	ADD	L4 and L5 Left	L5 and S1 Left	2014-10	-
02/0216	ND plus	ES/SAF/FAS	ADD	L5 and S1 Right	L4 and L5 Right	2015-04-06	23
02/0217	SC	ES/SAF/FAS	HD	L4 and L5 Left		2014-11-15	195
02/0218	ND basic	ES/SAF	ADD	L5 and S1 Right	L4 and L5 Right	2014	546
02/0219	ND basic	ES/SAF/FAS	HD	L5 and S1 Left		2015-01	162
02/0220	SC	ES/SAF/FAS	HD	L4 and L5 Left		2013	955
02/0221	ND plus	ES/SAF	HD	L4 and L5 Left		2015-05	124
02/0222	ND plus	ES/SAF	HD	L5 and S1 Right		2015-06	102
02/0223	ND basic	ES/SAF/FAS	HD	L5 and S1 Right		2015-07	182
02/0224	ND plus	ES/SAF	HD	L5 and S1 Right		2015-05	243

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

For computation of 'Time since start of complaints': missing day was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_anam.lst / l_anam.sas

Page 4 of 8

-continued on next page-

Listing 16.2.1.5: Anamnesis at Screening - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Type of degenerated lumbar disc	Location of herniated disc	Location of adjacent disc	Start Date of current complaints	Time since start of complaints (days)
04/0401	SC	ES/SAF/FAS	ADD	L5 and S1 Right	L4 and L5 Left/Right	2015-05-01	61
06/0601		ES	ADD	L5 and S1 Left	L4 and L5 Left	- -	-
06/0602	ND plus	ES/SAF/FAS	HD	L3 and L4 Left		- -	-
06/0604	ND basic	ES/SAF	HD	L5 and S1 Right		2014-07	120
06/0605	ND plus	ES/SAF	HD	L5 and S1 Left		2014-10-12	61
06/0606	SC	ES/SAF/FAS	HD	L5 and S1 Right		2013-11	411
06/0607	ND plus	ES/SAF/FAS	HD	L5 and S1 Right		2014-11	81
06/0608	SC	ES/SAF	HD	L5 and S1 Right		2015-01-24	6
06/0609	ND basic	ES/SAF	ADD	L5 and S1 Right	L4 and L5 Left	2015-01	106
06/0610	ND plus	ES/SAF/FAS	ADD	L5 and S1 Left	L4 and L5 Left	2015-02	145
06/0611		ES	HD	L5 and S1 Left		2015-07-06	10
06/0612	ND plus	ES/SAF/FAS	HD	L4 and L5 Left		2015-06-28	18
06/0613	SC	ES/SAF/FAS	HD	L3 and L4 Right		2015-07-17	4
06/0614	ND plus	ES/SAF/FAS	ADD	L5 and S1 Right	L4 and L5 Right	2015-08-04	15
06/0615	ND basic	ES/SAF	ADD	L4 and L5 Right	L3 and L4 Right	2015-08-11	15
06/0616		ES	ADD	L4 and L5 Right	L5 and S1	2015-10	40
06/0617	ND plus	ES/SAF	ADD	L4 and L5 Right	L3 and L4	2015-12-13	10
06/0618		ES	HD	L5 and S1 Right		2015-11	79
06/0619	ND basic	ES/SAF/FAS	HD	L4 and L5 Right		2015-11	115

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

For computation of 'Time since start of complaints': missing day was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_anam.lst / l_anam.sas

Page 5 of 8

-continued on next page-

Listing 16.2.1.5: Anamnesis at Screening - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Type of degenerated lumbar disc	Location of herniated disc	Location of adjacent disc	Start Date of current complaints	Time since start of complaints (days)
06/0620	SC	ES/SAF/FAS	ADD	L5 and S1 Left	L4 and L5 Right	2015-08	208
07/0701	ND plus	ES/SAF/FAS	HD	L5 and S1 Right		2014-04-01	220
07/0702	SC	ES/SAF/FAS	HD	L5 and S1 Right		2015-01-08	13
07/0703	ND plus	ES/SAF/FAS	ADD	L4 and L5 Right	L3 and L4 Left/Right	2015-02-22	10
07/0704	ND basic	ES/SAF/FAS	HD	L4 and L5 Left		2015-04-10	98
07/0705		ES	HD	L5 and S1 Right		2015-08-07	7
07/0706	SC	ES/SAF/FAS	HD	L3 and L4 Right		2015-11-01	31
07/0707		ES	HD	L5 and S1 Left		2015-12-01	-
08/0801	SC	ES/SAF/FAS	HD	L4 and L5 Left		2014-10-01	34
08/0802	ND plus	ES/SAF/FAS	HD	L3 and L4 Right		2014-09-01	88
08/0803	ND basic	ES/SAF/FAS	HD	L5 and S1 Left		2014-12-26	62
08/0804	ND plus	ES/SAF/FAS	HD	L3 and L4 Left		2015-05-19	16
08/0805	ND basic	ES/SAF/FAS	HD	L2 and L3 Right		2015-04-15	72
08/0806	ND plus	ES/SAF/FAS	HD	L2 and L3 Right		2015-06-20	19
08/0807	ND plus	ES/SAF/FAS	HD	L4 and L5 Right		2015-04-15	219
08/0808	SC	ES/SAF/FAS	HD	L3 and L4 Right		2015-11-21	13
09/0901	SC	ES/SAF/FAS	HD	L5 and S1 Right		2014-08-04	88
09/0902		ES	HD	L5 and S1 Right		2014-10-06	-
09/0903	ND plus	ES/SAF	HD	L3 and L4 Right		2014-09-29	53

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

For computation of 'Time since start of complaints': missing day was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_anam.lst / l_anam.sas

Page 6 of 8

-continued on next page-

Listing 16.2.1.5: Anamnesis at Screening - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Type of degenerated lumbar disc	Location of herniated disc	Location of adjacent disc	Start Date of current complaints	Time since start of complaints (days)
09/0904	ND basic	ES/SAF/FAS	HD	L4 and L5 Left		2013-07-01	589
09/0905	ND plus	ES/SAF/FAS	HD	L4 and L5 Right		2015-03-13	7
09/0906		ES	HD	L4 and L5 Right		2015-03-18	-
09/0907	SC	ES/SAF/FAS	HD	L5 and S1 Left		2015-02-15	60
09/0908	ND basic	ES/SAF/FAS	HD	L4 and L5 Left		2014-12-25	134
09/0909	ND plus	ES/SAF/FAS	HD	L5 and S1 Left		2015-03-30	44
09/0910	ND plus	ES/SAF	HD	L5 and S1 Left		2015-07-26	38
09/0911	ND plus	ES/SAF/FAS	HD	L5 and S1 Right		2014-12-15	309
09/0912	ND plus	ES/SAF/FAS	HD	L5 and S1 Right		2015-09-19	32
09/0913	ND basic	ES/SAF/FAS	HD	L4 and L5 Right		2015-11-12	19
09/0914	SC	ES/SAF/FAS	HD	L5 and S1 Left		2015-10-23	76
09/0915	ND basic	ES/SAF/FAS	HD	L4 and L5 Right		2015-10-01	98
09/0916	SC	ES/SAF/FAS	HD	L5 and S1 Right		2015-12-12	74
10/1001		ES	HD	L4 and L5 Right		2015-08	-
11/1101	ND plus	ES/SAF/FAS	ADD	L5 and S1 Left	L4 and L5 Left/Right	2014-12-22	23
11/1102	ND basic	ES/SAF/FAS	HD	L5 and S1 Left		2015-01-15	96
11/1103	SC	ES/SAF/FAS	HD	L5 and S1 Left		2015-01	215
11/1104	ND plus	ES/SAF/FAS	HD	L5 and S1 Left		2016-01-01	67
12/1201	ND plus	ES/SAF/FAS	HD	L5 and S1 Right		2015-06	99

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

For computation of 'Time since start of complaints': missing day was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_anam.lst / l_anam.sas

Page 7 of 8

-continued on next page-

Listing 16.2.1.5: Anamnesis at Screening - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Type of degenerated lumbar disc	Location of herniated disc	Location of adjacent disc	Start Date of current complaints	Time since start of complaints (days)
12/1202		ES		L4 and L5 Left		2015-07	-
13/1301	ND plus	ES/SAF/FAS	ADD	L5 and S1 Right	L4 and L5 Right	2015-04-01	27
13/1302	ND plus	ES/SAF/FAS	HD	L4 and L5 Right		2015-05-05	8
13/1303	SC	ES/SAF/FAS	HD	L5 and S1 Right		2015-06-18	12
13/1304	ND basic	ES/SAF/FAS	HD	L5 and S1 Left		2015-06-17	16
13/1305	ND plus	ES/SAF	ADD	L5 and S1 Right	L4 and L5 Right	2015-10-10	6

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

For computation of 'Time since start of complaints': missing day was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_anam.lst / l_anam.sas

Listing 16.2.1.6: Medical and Surgical History during the last year - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Medical or Surgical History	Reported Term	Dictionary-derived term	System Organ Class	Start date	End date	Ongoing
01/0103	ND basic	ES/SAF/FAS	MH	OM Arthrosis right shoulder	Osteoarthritis	Musculoskeletal and connective tissue disorders	UN		Yes
			SH	Impingment Syndrom	Rotator cuff syndrome	Musculoskeletal and connective tissue disorders	2010		
01/0104	ND basic	ES/SAF/FAS	MH	APPENDIZITIS	Appendicitis	Infections and infestations	2012-07	2012-07	
			SH	APPENDECTOMY	Appendicectomy	Surgical and medical procedures	2012-07		
01/0106	ND plus	ES/SAF/FAS	MH	Asthma bronchiale	Asthma	Respiratory, thoracic and mediastinal disorders	2003		Yes
			MH	Allergy wheat flour	Food allergy	Immune system disorders	2000		Yes
01/0107	ND plus	ES/SAF/FAS	MH	gynaecomastia	Gynaecomastia	Reproductive system and breast disorders	2012-07	2012-09	
			MH	hypertension (arterial)	Hypertension	Vascular disorders	2003		Yes
			MH	hypothyroidism (substantial)	Hypothyroidism	Endocrine disorders	2009-01		Yes
			SH	mastectomy	Mastectomy	Surgical and medical procedures	2012-09		
01/0110	ND basic	ES/SAF/FAS	MH	Asthma	Asthma	Respiratory, thoracic and mediastinal disorders	2011		Yes
			MH	Hypothyroidism	Hypothyroidism	Endocrine disorders	2011-10		Yes
01/0111	ND plus	ES/SAF/FAS	MH	Hypercholesterolemia	Hypercholesterolaemia	Metabolism and nutrition disorders	2003		Yes
01/0113	ND basic	ES/SAF/FAS	MH	hay fever	Seasonal allergy	Immune system disorders	2002		Yes
01/0114	ND basic	ES/SAF/FAS	MH	Hypothyroidism	Hypothyroidism	Endocrine disorders	2000-04		Yes
			MH	Migraine	Migraine	Nervous system disorders	2010		Yes
01/0116	ND basic	ES/SAF	MH	Palllenosis	Seasonal allergy	Immune system disorders	UN		Yes
01/0119	ND basic	ES/SAF/FAS	MH	Hypercholesterolanaemia	Hypercholesterolaemia	Metabolism and nutrition disorders	2013-05		Yes
01/0123	ND plus	ES/SAF/FAS	MH	ANXIETY DISORDER	Anxiety disorder	Psychiatric disorders	2014-01		Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

MH = Medical History, SH = Surgical History

Clinipace: 14DEC21 / 7:42 / l_mh.lst / l_mh.sas

Listing 16.2.1.6: Medical and Surgical History during the last year - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Medical or Surgical History	Reported Term	Dictionary-derived term	System Organ Class	Start date	End date	Ongoing
01/0123	ND plus	ES/SAF/FAS	SH	ABSCESS REMOVAL (CUTANEUS, SOCRUM, RIGHT)	Abscess drainage	Surgical and medical procedures	2014-01		
01/0125	SC	ES/SAF/FAS	SH	Dental implant, mandible, left	Dental implantation	Surgical and medical procedures	2013-10		
01/0126	ND basic	ES/SAF/FAS	MH	ALLERGY: LIDAPRIM	Drug hypersensitivity	Immune system disorders	UN		Yes
01/0129	SC	ES/SAF/FAS	SH	ARTHROSCOPY LEFT KNEE	Arthroscopy	Investigations	2013-09		
01/0135	ND plus	ES/SAF/FAS	MH	HYPERTENSION	Hypertension	Vascular disorders	UNK		Yes
01/0136	ND basic	ES/SAF/FAS	MH MH SH	HYPOTHYREOSIS HYPERTENSION CHOLECYSTECTOMY	Hypothyroidism Hypertension Cholecystectomy	Endocrine disorders Vascular disorders Surgical and medical procedures	2006 2006 2011		Yes Yes
01/0139	ND plus	ES/SAF/FAS	MH	HYPERTENSION	Hypertension	Vascular disorders	UN		Yes
01/0140	ND basic	ES/SAF/FAS	MH	FRUCTOSE INTOLERANCE	Fructose intolerance	Metabolism and nutrition disorders	UNK		Yes
01/0144	ND basic	ES/SAF/FAS	MH	Conjunctivitis	Conjunctivitis	Infections and infestations	2015-06	2015-06	
01/0145	ND plus	ES/SAF/FAS	MH	ASTHMA	Asthma	Respiratory, thoracic and mediastinal disorders	UNK		Yes
01/0146	SC	ES/SAF/FAS	MH MH MH	HYPERTENSION DEPRESSION neuropathic pain left hand	Hypertension Depression Neuralgia	Vascular disorders Psychiatric disorders Nervous system disorders	2010 2010 2010		Yes Yes
01/0148	ND plus	ES/SAF/FAS	MH	ASTHMA BRONCHIALE	Asthma	Respiratory, thoracic and mediastinal disorders	2000		Yes
01/0150		ES	MH	HYPERTENSION	Hypertension	Vascular disorders	2013		Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

MH = Medical History, SH = Surgical History

Clinipace: 14DEC21 / 7:42 / l_mh.lst / l_mh.sas

Listing 16.2.1.6: Medical and Surgical History during the last year - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Medical or Surgical History	Reported Term	Dictionary-derived term	System Organ Class	Start date	End date	Ongoing
01/0150		ES	SH	VEIN SURGERY BOTH LEGS	Venous operation	Surgical and medical procedures	2014-11		
01/0152	SC	ES/SAF/FAS	MH	Postmenopausal complaints (substituted)	Menopausal symptoms	Reproductive system and breast disorders	UN		Yes
02/0201	ND plus	ES/SAF/FAS	SH	Teeth (implants)	Dental implantation	Surgical and medical procedures	2012-06		
02/0205	ND basic	ES/SAF/FAS	MH	Disorder lipid metabolism	Lipid metabolism disorder	Metabolism and nutrition disorders	2008		Yes
			MH	Hypertension	Hypertension	Vascular disorders	2008		Yes
			MH	Disorder urea metabolism	Urea cycle disorder	Congenital, familial and genetic disorders	2008		Yes
02/0206	ND plus	ES/SAF/FAS	MH	Allergy, Amoxicillin	Drug hypersensitivity	Immune system disorders	1987		Yes
02/0207		ES	MH	Allergy Kiwi	Food allergy	Immune system disorders	UN		Yes
02/0215		ES	MH	allergic rhinitis	Rhinitis allergic	Respiratory, thoracic and mediastinal disorders	2015		Yes
02/0216	ND plus	ES/SAF/FAS	MH	hypothreose	Hypothyroidism	Endocrine disorders	2009		Yes
			MH	thyroid removal	Thyroidectomy	Surgical and medical procedures	2009		Yes
02/0217	SC	ES/SAF/FAS	SH	L5 re. Infiltration	Infiltration anaesthesia	Surgical and medical procedures	2015-05		
02/0221	ND plus	ES/SAF	MH	Tachycardie	Tachycardia	Cardiac disorders	2014-12		
02/0222	ND plus	ES/SAF	MH	Hypertension	Hypertension	Vascular disorders	1995		Yes
02/0223	ND basic	ES/SAF/FAS	MH	Depression	Depression	Psychiatric disorders	2013		Yes
04/0401	SC	ES/SAF/FAS	MH	Lumboischialgia	Sciatica	Nervous system disorders	2014-11		Yes
06/0602	ND plus	ES/SAF/FAS	MH	Postmenopausal	Postmenopause	Social circumstances	2012-01		Yes
			MH	Depression	Depression	Psychiatric disorders	1998		Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

MH = Medical History, SH = Surgical History

Clinipace: 14DEC21 / 7:42 / l_mh.lst / l_mh.sas

Listing 16.2.1.6: Medical and Surgical History during the last year - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Medical or Surgical History	Reported Term	Dictionary-derived term	System Organ Class	Start date	End date	Ongoing
06/0602	ND plus	ES/SAF/FAS	MH SH	Hypothyreodism meniscal-op left	Hypothyroidism Meniscus operation	Endocrine disorders Surgical and medical procedures	UNK 2012-08		Yes
06/0605	ND plus	ES/SAF	MH MH	chronic depression hypertension	Depression Hypertension	Psychiatric disorders Vascular disorders	2009 2004		Yes Yes
06/0606	SC	ES/SAF/FAS	MH	Insomnia	Insomnia	Psychiatric disorders	2013	2015-11	
06/0607	ND plus	ES/SAF/FAS	MH	Heartburn	Dyspepsia	Gastrointestinal disorders	2000		Yes
06/0609	ND basic	ES/SAF	MH MH	Lumbo isatic disease S1 Hay fever	Sciatica Seasonal allergy	Nervous system disorders Immune system disorders	2015-04 UNK	UNK UNK	
06/0610	ND plus	ES/SAF/FAS	MH MH	Hypothyroidism Depression	Hypothyroidism Depression	Endocrine disorders Psychiatric disorders	2010 2014	2015-12	Yes
06/0611		ES	MH MH MH MH MH	Ibuprofen (pain) Pantozol (Protection stomach) Travenol (pain) Capros (pain) Mono Embolex (thrombosis prophylaxis)	Pain Prophylaxis Pain Pain Thrombosis prophylaxis	General disorders and administration site conditions Surgical and medical procedures General disorders and administration site conditions General disorders and administration site conditions Surgical and medical procedures	2015-07 2015-07 2015-07 2015-07 2015-07	Yes Yes Yes Yes Yes	
06/0612	ND plus	ES/SAF/FAS	MH MH MH	Pneumonia Hypertension Asthma	Pneumonia Hypertension Asthma	Infections and infestations Vascular disorders Respiratory, thoracic and mediastinal disorders	2015-01 2012 1997	2015-01	 Yes Yes
06/0616		ES	MH	hypertension	Hypertension	Vascular disorders	2015-10		Yes
06/0619	ND basic	ES/SAF/FAS	MH	Hypertonie	Hypertension	Vascular disorders	2013		Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set
MH = Medical History, SH = Surgical History
Clinipace: 14DEC21 / 7:42 / l_mh.lst / l_mh.sas

Listing 16.2.1.6: Medical and Surgical History during the last year - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Medical or Surgical History	Reported Term	Dictionary-derived term	System Organ Class	Start date	End date	Ongoing
07/0703	ND plus	ES/SAF/FAS	MH	bronchial asthma	Asthma	Respiratory, thoracic and mediastinal disorders	1990-12		Yes
07/0705		ES	MH MH	Schlafstörungen Gastritis	Sleep disorder Gastritis	Psychiatric disorders Gastrointestinal disorders	2014-07 2010		Yes Yes
07/0706	SC	ES/SAF/FAS	MH	Fibromyalgie	Fibromyalgia	Musculoskeletal and connective tissue disorders	2012		Yes
			MH MH	depressive Episoden Hypertension	Depression Hypertension	Psychiatric disorders Vascular disorders	1996 UNK		Yes Yes
08/0801	SC	ES/SAF/FAS	MH	Asthma bronchiale	Asthma	Respiratory, thoracic and mediastinal disorders	2014-01		Yes
			MH MH MH	Art. Hypertonie Depression Sleep disorder	Hypertension Depression Sleep disorder	Vascular disorders Psychiatric disorders Psychiatric disorders	2000-01 2012-01 2012-01		Yes Yes Yes
08/0802	ND plus	ES/SAF/FAS	MH	Migrane	Migraine	Nervous system disorders	2000		Yes
08/0803	ND basic	ES/SAF/FAS	MH MH	headaches pollinosis	Headache Seasonal allergy	Nervous system disorders Immune system disorders	2014-07 2014-05		Yes Yes
08/0804	ND plus	ES/SAF/FAS	MH	past medical nausea	Nausea	Gastrointestinal disorders	2015-06	2015-06	
08/0805	ND basic	ES/SAF/FAS	MH MH	Hypothyreosis Anxiety	Hypothyroidism Anxiety	Endocrine disorders Psychiatric disorders	2010 UNK		Yes Yes
08/0806	ND plus	ES/SAF/FAS	MH	recurrent throat infections	Pharyngitis	Infections and infestations	2014-11	2015-02	
			MH	claustrophobia	Claustrophobia	Psychiatric disorders	2010-07		Yes
08/0807	ND plus	ES/SAF/FAS	MH	Colon polyps	Large intestine polyp	Gastrointestinal disorders	2015-03	2015-03	
			SH	Polypectomy	Polypectomy	Surgical and medical procedures	2015-03		
08/0808	SC	ES/SAF/FAS	MH MH	Hypertonie Hypothyreosis	Hypertension Hypothyroidism	Vascular disorders Endocrine disorders	UNK UNK		Yes Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

MH = Medical History, SH = Surgical History

Clinipace: 14DEC21 / 7:42 / l_mh.lst / l_mh.sas

Listing 16.2.1.6: Medical and Surgical History during the last year - all enrolled subjects

Site/Subject ID	Treatment group	Analysis Set	Medical or Surgical History	Reported Term	Dictionary-derived term	System Organ Class	Start date	End date	Ongoing
09/0907	SC	ES/SAF/FAS	MH	Lumbalgie	Back pain	Musculoskeletal and connective tissue disorders	2014-11	2014-12	
09/0909	ND plus	ES/SAF/FAS	MH MH	Hypothyreodism Hypertension	Hypothyroidism Hypertension	Endocrine disorders Vascular disorders	1985 2014-11		Yes Yes
09/0910	ND plus	ES/SAF	MH	Hypertension	Hypertension	Vascular disorders			
09/0911	ND plus	ES/SAF/FAS	MH	Back pain	Back pain	Musculoskeletal and connective tissue disorders	2014-12	2015-10	
11/1101	ND plus	ES/SAF/FAS	MH SH	Zahnextraktion Laparoskopie	Tooth extraction Laparoscopy	Surgical and medical procedures Investigations	2014-11 2014-12	2014-12	
11/1103	SC	ES/SAF/FAS	MH MH	CT gestützt PRT depression	Nerve block Depression	Surgical and medical procedures Psychiatric disorders	2015-07 2015-07	2015-07	Yes
11/1104	ND plus	ES/SAF/FAS	MH MH	Hypertonic hay fever	Hypertension Seasonal allergy	Vascular disorders Immune system disorders	2015-10 UNK		Yes Yes
12/1201	ND plus	ES/SAF/FAS	MH MH MH MH MH MH	Koronar arterial desease Hypothyreosis Sterilization Arteriosklerosis arterial hypertension Hypercholesterinaemi a	Coronary artery disease Hypothyroidism Sterilisation Arteriosclerosis Hypertension Hypercholesterolaemi a	Cardiac disorders Endocrine disorders Surgical and medical procedures Vascular disorders Vascular disorders Metabolism and nutrition disorders	2014-08 2008-10 1993 2008-07 2008-10		Yes Yes Yes Yes Yes
13/1301	ND plus	ES/SAF/FAS	MH	Cardiac arrhythmia	Arrhythmia	Cardiac disorders	2012		Yes
13/1302	ND plus	ES/SAF/FAS	MH	hypertension	Hypertension	Vascular disorders	2007-06		Yes
13/1303	SC	ES/SAF/FAS	SH	fracture of jaw	Jaw fracture	Injury, poisoning and procedural complications	2015-01		
13/1304	ND basic	ES/SAF/FAS	MH	acute respiretory disease	Respiratory disorder	Respiratory, thoracic and mediastinal disorders	2015-04	2015-05	

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

MH = Medical History, SH = Surgical History

Clinipace: 14DEC21 / 7:42 / l_mh.lst / l_mh.sas

Listing 16.2.1.7: Surgery and Tissue Explant - all enrolled subjects

Site/Subject ID	Type of degenerative lumbar disc	Date of procedure	Start/End Time	Location herniated disc between	Location adjacent disc between	Practicability of surgical instruments acceptable?	Use of micro-scope	Blood content (ml)	Technique haemostasis	Amount of tissue (g)	_Anulus defect_ Type Size	Description of removed sequester	Post-operative length of hospitalization (days)
01/0103	HD	2012-10-18	08:45/09:57	L4/L5/Right		Yes	Y	150.0	Sponge and Bipolar epidural coagulation	0.972		Loose sequester	6
01/0104	ADD	2012-10-24	08:20/09:05	L5/S1/Right	L4/L5/Right	Yes	Y	100.0	Sponge	4.804		Loose sequester	5
01/0106	HD	2012-11-28	08:18/08:50	L5/S1/Right		Yes	Y	20.0	Bipolar epidural coagulation	1.941		Loose sequester, Compact tissue	7
01/0107	HD	2013-01-09	08:20/09:00	L4/L5/Right		Yes	Y	20.0	Sponge and Bipolar epidural coagulation	0.752		Loose sequester	7
01/0108	HD	2013-01-10	10:30/11:10	L5/S1/Left		Yes	Y	50.0	Sponge and Bipolar epidural coagulation	1.015			6
01/0110	ADD	2013-01-24	08:26/09:12	L5/S1/Right	L4/L5/Right	Yes	Y	100.0	Sponge and Bipolar epidural coagulation	2.261		Loose sequester, Compact tissue	7
01/0111	HD	2013-03-12	08:19/08:47	L5/S1/Left		Yes	Y	10.0	Bipolar epidural coagulation	1.677		Loose sequester, Compact tissue	15
01/0112	HD	2013-03-26	11:35/12:20	L5/S1/Right		Yes	Y	50.0	Sponge and Bipolar epidural coagulation	5.725		Tight fitting sequester	5

Listing 16.2.1.7: Surgery and Tissue Explant - all enrolled subjects

Site/Subject ID	Type of degenerative lumbar disc	Date of procedure	Start/End Time	Location herniated disc between	Location adjacent disc between	Practicability of surgical instruments acceptable?	Use of micro-scope	Blood content (ml)	Technique haemostasis	Amount of tissue (g)	_Anulus defect_ Type Size	Description of removed sequester	Post-operative length of hospitalization (days)
01/0113	HD	2013-05-23	14:07/15:11	L5/S1/Left		Yes	Y	150.0	Sponge and Bipolar epidural coagulation	1.200		Loose sequester	6
01/0114	HD	2013-06-11	08:24/09:10	L4/L5/Left		Yes	Y	5.0	Bipolar epidural coagulation	1.550		Loose sequester	7
01/0115	HD	2013-06-12	08:05/08:55	L5/S1/Left		Yes	Y	50.0	Bipolar epidural coagulation	3.848		Loose sequester	7
01/0116	ADD	2013-06-18	11:00/12:40	L5/S1/Right	L4/L5/Right	Yes	Y	1.0	Bipolar epidural coagulation	2.386		Tight fitting sequester, Other	5
01/0118	HD	2013-07-10	08:35/09:36	L5/S1/Left		Yes	Y	50.0	Bipolar epidural coagulation	0.474		Tight fitting sequester	8
01/0119	HD	2013-07-23	08:32/09:45	L5/S1/Left		Yes	Y	50.0	Bipolar epidural coagulation	1.243		Loose sequester	7
01/0121	HD	2013-10-15	08:20/09:48	L5/S1/Right		Yes	Y	50.0	Bipolar epidural coagulation	0.873		Tight fitting sequester, Compact tissue	6
01/0122	HD	2013-09-26	08:25/09:48	L5/S1/Left		Yes	Y	150.0	Sponge and Bipolar epidural coagulation	0.043		Loose sequester	7

Listing 16.2.1.7: Surgery and Tissue Explant - all enrolled subjects

Site/Subject ID	Type of degenerative lumbar disc	Date of procedure	Start/End Time	Location herniated disc between	Location adjacent disc between	Practicability of surgical instruments acceptable?	Use of micro-scope	Blood content (ml)	Technique haemostasis	Amount of tissue (g)	_Anulus defect_ Type	Size	Description of removed sequester	Post-operative length of hospitalization (days)
01/0123	HD	2014-09-16	13:16/14:04	L4/L5/Right		Yes	Y	150.0	Sponge and Bipolar epidural coagulation	0.345	Slit	0 to 3 mm	Loose sequester	6
01/0124	HD	2014-11-06	08:20/09:07	L5/S1/Right		Yes	Y	100.0	Sponge and Bipolar epidural coagulation	1.444	Total defect (hole)	> 6 mm	Loose sequester	6
01/0125	HD	2014-10-07	12:28/13:03	L5/S1/Left		Yes	Y	300.0	Sponge and Bipolar epidural coagulation	2.660	Torn	3 to 6 mm	Loose sequester	9
01/0126	HD	2014-10-08	12:40/13:20	L4/L5/Left		Yes	Y	180.0	Bipolar epidural coagulation	1.290	Total defect (hole)	0 to 3 mm	Loose sequester	11
01/0127	HD	2014-10-20	14:55/15:40	L5/S1/Right		Yes	Y	150.0	Bipolar epidural coagulation	3.277	Slit	3 to 6 mm	Loose sequester	6
01/0128	ADD	2014-10-21	13:51/14:40	L4/L5/Right	L5/S1/NA	Yes	Y	150.0	Bipolar epidural coagulation	-	Total defect (hole)	> 6 mm	Compact tissue	7
01/0129	HD	2014-10-29	08:29/09:46	L4/L5/Right		Yes	Y	50.0	Sponge and Bipolar epidural coagulation	2.340	Slit	0 to 3 mm	Loose sequester	8
01/0130	HD	2014-11-20	08:20/10:40	L4/L5/Left		Yes	Y	200.0	Sponge and Bipolar epidural coagulation	0.660	Torn	0 to 3 mm	Tight fitting sequester, Compact tissue	5

Listing 16.2.1.7: Surgery and Tissue Explant - all enrolled subjects

Site/Subject ID	Type of degenerative lumbar disc	Date of procedure	Start/End Time	Location herniated disc between	Location adjacent disc between	Practicability of surgical instruments acceptable?	Use of micro-scope	Blood content (ml)	Technique haemostasis	Amount of tissue (g)	_Anulus defect_ Type	Size	Description of removed sequester	Post-operative length of hospitalization (days)
01/0131	HD	2014-12-01	09:13/10:25	L4/L5/Right		Yes	Y	100.0	Sponge and Bipolar epidural coagulation	2.125	Total defect (hole)	3 to 6 mm	Loose sequester	12
01/0132	HD	2014-12-02	10:45/12:30	L4/L5/Left		Yes	Y	100.0	Bipolar epidural coagulation	2.240	Total defect (hole)	> 6 mm	Compact tissue	5
01/0133	HD	2014-12-16	14:25/15:35	L4/L5/Left		Yes	Y	100.0	Bipolar epidural coagulation	0.620	Slit	0 to 3 mm	Loose sequester, Compact tissue	8
01/0134	HD	2014-12-17	08:20/09:40	L5/S1/Left		Yes	Y	50.0	Sponge and Bipolar epidural coagulation	1.290	Total defect (hole)	> 6 mm	Compact tissue	6
01/0135	HD	2015-01-15	08:25/10:15	L5/S1/Right		Yes	Y	50.0	Sponge and Bipolar epidural coagulation	0.256	Torn	0 to 3 mm	Loose sequester, Compact tissue	8
01/0136	HD	2015-02-23	12:50/14:10	L4/L5/Right		Yes	Y	100.0	Sponge and Bipolar epidural coagulation	0.361	Total defect (hole)	> 6 mm	Fibrousness tissue	5
01/0137	HD	2015-02-26	12:00/13:30	L4/L5/Left		Yes	Y	50.0	Sponge and Bipolar epidural coagulation	1.293	Slit	0 to 3 mm	Loose sequester, Compact tissue	6

Listing 16.2.1.7: Surgery and Tissue Explant - all enrolled subjects

Site/Subject ID	Type of degenerative lumbar disc	Date of procedure	Start/End Time	Location herniated disc between	Location adjacent disc between	Practicability of surgical instruments acceptable?	Use of micro-scope	Blood content (ml)	Technique haemostasis	Amount of tissue (g)	_Anulus defect_ Type	Size	Description of removed sequester	Post-operative length of hospital-ization (days)
01/0138	HD	2015-03-09	13:28/14:35	L5/S1/Right		Yes	Y	100.0	Sponge and Bipolar epidural coagulation	0.001	Slit	0 to 3 mm	Tight fitting sequester	6
01/0139	HD	2015-03-10	11:25/13:25	L5/S1/Right		Yes	Y	100.0	Sponge and Bipolar epidural coagulation	1.990	Total defect (hole)	3 to 6 mm	Tight fitting sequester, Compact tissue	9
01/0140	HD	2015-05-12	13:03/14:13	L5/S1/Right		Yes	Y	10.0	Sponge and Bipolar epidural coagulation	0.780	Slit	3 to 6 mm	Loose sequester, Compact tissue	6
01/0141	HD	2015-05-27	08:15/09:15	L4/L5/Right		Yes	Y	150.0	Bipolar epidural coagulation	2.800	Total defect (hole)	0 to 3 mm	Tight fitting sequester	6
01/0142	HD	2015-05-27	13:15/15:25	L5/S1/Right		Yes	Y	100.0	Sponge and Bipolar epidural coagulation	0.239	Torn	0 to 3 mm	Loose sequester, Compact tissue	6
01/0143	HD	2015-06-17	08:36/09:52	L4/L5/Left		Yes	Y	50.0	Bipolar epidural coagulation	0.720	Slit	3 to 6 mm	Loose sequester, Compact tissue	6
01/0144	HD	2015-06-24	14:56/15:36	L5/S1/Left		Yes	Y	50.0	Sponge and Bipolar epidural coagulation	2.351	Total defect (hole)	3 to 6 mm	Loose sequester, Compact tissue	6

Listing 16.2.1.7: Surgery and Tissue Explant - all enrolled subjects

Site/Subject ID	Type of degenerative lumbar disc	Date of procedure	Start/End Time	Location herniated disc between	Location adjacent disc between	Practicability of surgical instruments acceptable?	Use of micro-scope	Blood content (ml)	Technique haemostasis	Amount of tissue (g)	_Anulus defect_ Type	Size	Description of removed sequester	Post-operative length of hospitalization (days)
01/0145	HD	2015-07-16	08:25/09:30	L5/S1/Right		Yes	Y	50.0	Sponge and Bipolar epidural coagulation	0.118	Torn	0 to 3 mm	Compact tissue	7
01/0146	HD	2015-07-16	10:45/12:00	L5/S1/Left		Yes	Y	50.0	Bipolar epidural coagulation	0.931	Slit	3 to 6 mm	Loose sequester, Compact tissue	6
01/0147	HD	2015-08-20	11:45/13:00	L4/L5/Left		Yes	Y	50.0	Sponge and Bipolar epidural coagulation	0.243	Torn	0 to 3 mm	Loose sequester	7
01/0148	HD	2015-10-22	08:26/08:52	L5/S1/Right		Yes	Y	50.0	Bipolar epidural coagulation	2.855	Slit	0 to 3 mm	Loose sequester, Compact tissue	6
01/0149	HD	2015-12-03	08:30/09:10	L4/L5/Left		Yes	Y	20.0	Sponge and Bipolar epidural coagulation	1.644	Slit	0 to 3 mm	Loose sequester, Compact tissue	7
01/0150	HD	2016-02-03	10:30/12:30	L4/L5/Left		Yes	Y	50.0	Sponge and Bipolar epidural coagulation	-	NA			-
01/0151	ADD	2016-03-03	08:30/09:10	L5/S1/Right	L4/L5/Right	Yes	Y	50.0	Bipolar epidural coagulation	2.044	Slit	3 to 6 mm	Loose sequester, Compact tissue	7

Listing 16.2.1.7: Surgery and Tissue Explant - all enrolled subjects

Site/Subject ID	Type of degenerative lumbar disc	Date of procedure	Start/End Time	Location herniated disc between	Location adjacent disc between	Practicability of surgical instruments acceptable?	Use of micro-scope	Blood content (ml)	Technique haemostasis	Amount of tissue (g)	_Anulus defect_ Type Size	Description of removed sequester	Post-operative length of hospitalization (days)
01/0152	HD	2016-03-03	08:20/09:05	L5/S1/Left		Yes	Y	50.0	Bipolar epidural coagulation	0.906	Torn 3 to 6 mm	Tight fitting sequester, Compact tissue	6
01/0153	ADD	2016-03-21	08:55/09:40	L5/S1/Right	L4/L5/Right	Yes	Y	50.0	Bipolar epidural coagulation	2.622	Total defect (hole) > 6 mm	Tight fitting sequester, Compact tissue	5
02/0201	ADD	2013-02-13	12:00/13:00	L4/L5/Left	L5/S1/UNK	Yes	Y	20.0	Sponge	0.299		Loose sequester, Fibrousness tissue	9
02/0202	HD	2013-03-20	13:35/14:30	L5/S1/Left		Yes	N	-	Bipolar epidural coagulation	1.327		Loose sequester	14
02/0203	ADD	2013-03-28	12:45/13:15	L4/L5/Left	L3/L4/Left	Yes	Y	100.0	Sponge and Bipolar epidural coagulation	3.996		Loose sequester	7
02/0204	ADD	2013-04-18	11:55/12:10	L5/S1/Left		Yes	Y	1.0	Sponge	2.490		Loose sequester	8
02/0205	HD	2013-04-18	12:10/12:30	L5/S1/Left		Yes	Y	50.0	Sponge and Bipolar epidural coagulation	1.044		Tight fitting sequester	10
02/0206	HD	2013-07-01	14:15/15:05	L4/L5/Left		Yes	Y	20.0	Sponge	1.913		Tight fitting sequester	14

Listing 16.2.1.7: Surgery and Tissue Explant - all enrolled subjects

Site/Subject ID	Type of degenerative lumbar disc	Date of procedure	Start/End Time	Location herniated disc between	Location adjacent disc between	Practicability of surgical instruments acceptable?	Use of micro-scope	Blood content (ml)	Technique haemostasis	Amount of tissue (g)	_Anulus defect_ Type	Size	Description of removed sequester	Post-operative length of hospitalization (days)
02/0207	HD	2013-07-24	13:15/14:30	L5/S1/Right		Yes	Y	-	Bipolar epidural coagulation	-				-
02/0208	ADD	2013-09-12	10:51/11:26	L5/S1/Left	L4/L5/Left/Right	Yes	Y	0.0	Sponge and Bipolar epidural coagulation	0.206			Tight fitting sequester, Loose sequester	10
02/0209	HD	2014-10-23	08:10/09:15	L4/L5/Right		Yes	Y	100.0	Sponge and Bipolar epidural coagulation	3.331	Total defect (hole)	3 to 6 mm	Fibrousness tissue	9
02/0210		2014-11-13	08:31/09:28	L4/L5/Left/Right		Yes	N	-		-	Total defect (hole)			-
02/0211	HD	2014-12-11	10:30/11:07	L5/S1/Right		Yes	Y	20.0	Bipolar epidural coagulation	3.590	Torn	3 to 6 mm	Compact tissue	9
02/0212	HD	2014-12-16	09:00/10:15	L3/L4/Left		Yes	Y	10.0	Bipolar epidural coagulation	1.340	Torn	3 to 6 mm	Fibrousness tissue	7
02/0213	HD	2014-12-18	12:30/13:30	L5/S1/Left		Yes	Y	0.0	Bipolar epidural coagulation	3.029	Torn	3 to 6 mm	Compact tissue	8
02/0214	HD	2015-02-25	12:25/13:20	L4/L5/Right		Yes	Y	50.0	Bipolar epidural coagulation	4.712	Total defect (hole)	3 to 6 mm	Fibrousness tissue	7

Listing 16.2.1.7: Surgery and Tissue Explant - all enrolled subjects

Site/Subject ID	Type of degenerative lumbar disc	Date of procedure	Start/End Time	Location herniated disc between	Location adjacent disc between	Practicability of surgical instruments acceptable?	Use of micro-scope	Blood content (ml)	Technique haemostasis	Amount of tissue (g)	_Anulus defect_ Type	Size	Description of removed sequester	Post-operative length of hospitalization (days)
02/0216	ADD	2015-04-28	12:30/13:15	L5/S1/Right	L4/L5/Right	Yes	Y	20.0	Bipolar epidural coagulation	1.805	Slit	3 to 6 mm	Loose sequester	9
02/0217	HD	2015-05-28	10:05/11:00	L4/L5/Left		Yes	Y	50.0	Sponge and Bipolar epidural coagulation	2.140	Slit	0 to 3 mm	Loose sequester	10
02/0218	ADD	2015-06-30	08:20/09:15	L5/S1/Right	L4/L5/Right	Yes	Y	50.0	Sponge	0.837	Slit	0 to 3 mm	Loose sequester	6
02/0219	HD	2015-06-11	14:25/15:30	L5/S1/Left		Yes	Y	10.0	Bipolar epidural coagulation	1.050	UNK	UNK	Loose sequester	9
02/0220	HD	2015-08-13	08:33/10:10	L4/L5/Left		Yes	Y	0.0	Bipolar epidural coagulation	3.468	Total defect (hole)	> 6 mm	Loose sequester	9
02/0221	HD	2015-09-01	08:24/09:20	L4/L5/Left		Yes	Y	-	Sponge	2.314	Torn	0 to 3 mm	Loose sequester	8
02/0222	HD	2015-09-10	11:25/12:35	L5/S1/Right		Yes	Y	30.0	Bipolar epidural coagulation	2.513	Torn	3 to 6 mm	Loose sequester	7
02/0223	HD	2015-12-29	08:34/09:10	L5/S1/Right		Yes	Y	10.0	Bipolar epidural coagulation	1.822	Torn	3 to 6 mm	Loose sequester	9
02/0224	HD	2015-12-29	08:20/08:50	L5/S1/Right		Yes	Y	20.0	Bipolar epidural coagulation	2.524	Slit	3 to 6 mm	Loose sequester	-

Listing 16.2.1.7: Surgery and Tissue Explant - all enrolled subjects

Site/Subject ID	Type of degenerative lumbar disc	Date of procedure	Start/End Time	Location herniated disc between	Location adjacent disc between	Practicability of surgical instruments acceptable?	Use of micro-scope	Blood content (ml)	Technique haemostasis	Amount of tissue (g)	_Anulus defect_ Type	Size	Description of removed sequester	Post-operative length of hospitalization (days)
04/0401	ADD	2015-06-30	08:59/12:28	L5/S1/Right	L4/L5/Left/Right	Yes	Y	50.0	Bipolar epidural coagulation	0.381	Slit	3 to 6 mm	Compact tissue	10
06/0602	HD	2013-07-23	08:58/09:46	L3/L4/Left		Yes	Y	150.0	Bipolar epidural coagulation	1.031			Fibrousness tissue	8
06/0604	HD	2014-10-28	08:30/09:13	L5/S1/Right		Yes	Y	50.0	Bipolar epidural coagulation	-	Total defect (hole)	3 to 6 mm	Loose sequester	10
06/0605	HD	2014-12-11	10:38/13:15	L5/S1/Left		Yes	Y	100.0	Bipolar epidural coagulation	1.396	Total defect (hole)	0 to 3 mm	Compact tissue	9
06/0606	HD	2014-12-16	14:27/15:50	L5/S1/Right		Yes	Y	150.0	Bipolar epidural coagulation	1.430	Torn	> 6 mm	Tight fitting sequester, Other	8
06/0607	HD	2015-01-20	08:33/09:38	L5/S1/Right		Yes	Y	150.0	Sponge and Bipolar epidural coagulation	0.680	Total defect (hole)	0 to 3 mm	Tight fitting sequester, Compact tissue	12
06/0608	HD	2015-01-29	10:04/10:59	L5/S1/Right		Yes	Y	80.0	Sponge and Bipolar epidural coagulation	2.970	Total defect (hole)	0 to 3 mm	Compact tissue	11
06/0609	ADD	2015-04-16	08:57/10:46	L5/S1/Right		Yes	Y	300.0	Bipolar epidural coagulation	3.405	Total defect (hole)	> 6 mm	Tight fitting sequester, Compact tissue	7

Listing 16.2.1.7: Surgery and Tissue Explant - all enrolled subjects

Site/Subject ID	Type of degenerative lumbar disc	Date of procedure	Start/End Time	Location herniated disc between	Location adjacent disc between	Practicability of surgical instruments acceptable?	Use of micro-scope	Blood content (ml)	Technique haemostasis	Amount of tissue (g)	_Anulus defect_ Type	Size	Description of removed sequester	Post-operative length of hospitalization (days)
06/0610	ADD	2015-06-25	10:00/11:35	L5/S1/Left	L4/L5/Left	Yes	Y	100.0	Sponge and Bipolar epidural coagulation	0.945	Slit	3 to 6 mm	Tight fitting sequester, Fibrousness tissue	8
06/0611	HD	2015-07-15	10:02/10:58	L5/S1/Left		Yes	Y	100.0	Sponge and Bipolar epidural coagulation	-	Slit	3 to 6 mm	Tight fitting sequester, Compact tissue	-
06/0612	HD	2015-07-15	12:13/13:44	L4/L5/Left		Yes	Y	200.0	Sponge and Bipolar epidural coagulation	1.417	Slit	> 6 mm	Loose sequester, Compact tissue	8
06/0613	HD	2015-07-20	12:01/13:02	L3/L4/Right		Yes	Y	100.0	Sponge and Bipolar epidural coagulation	1.976	Torn	0 to 3 mm	Loose sequester, Compact tissue	8
06/0614	ADD	2015-08-18	08:42/09:59	L5/S1/Right	L4/L5/Right	Yes	Y	75.0	Sponge and Bipolar epidural coagulation	3.074	Total defect (hole)	0 to 3 mm	Tight fitting sequester, Compact tissue	11
06/0615	ADD	2015-08-25	08:41/09:16	L4/L5/Right	L3/L4/Right	Yes	Y	25.0	Bipolar epidural coagulation	4.082	Total defect (hole)	0 to 3 mm	Loose sequester, Compact tissue	5
06/0616	ADD	2015-11-09	09:12/10:46	L4/L5/Right	L5/S1/	Yes	Y	100.0	Sponge and Bipolar epidural coagulation	-	Total defect (hole)	> 6 mm	Compact tissue, Other	-

Listing 16.2.1.7: Surgery and Tissue Explant - all enrolled subjects

Site/Subject ID	Type of degenerative lumbar disc	Date of procedure	Start/End Time	Location herniated disc between	Location adjacent disc between	Practicability of surgical instruments acceptable?	Use of micro-scope	Blood content (ml)	Technique haemostasis	Amount of tissue (g)	_Anulus defect_ Type	Size	Description of removed sequester	Post-operative length of hospitalization (days)
06/0617	ADD	2015-12-22	08:44/09:45	L4/L5/Right	L3/L4/	Yes	Y	50.0	Bipolar epidural coagulation	1.872	Torn	3 to 6 mm	Tight fitting sequester, Compact tissue	11
06/0618	HD	2016-01-18	09:03/10:22	L5/S1/Right		Yes	Y	450.0	Sponge and Bipolar epidural coagulation	-	Total defect (hole)	3 to 6 mm	Tight fitting sequester	-
06/0619	HD	2016-02-23	08:43/09:39	L4/L5/Right		Yes	Y	150.0	Sponge and Bipolar epidural coagulation	0.838	Total defect (hole)	0 to 3 mm	Loose sequester, Fibrousness tissue	7
06/0620	ADD	2016-02-24	08:30/09:40	L5/S1/Left	L4/L5/Right	Yes	Y	30.0	Sponge and Bipolar epidural coagulation	1.770	Total defect (hole)	3 to 6 mm	Tight fitting sequester, Compact tissue	8
07/0701	HD	2014-11-06	08:56/09:55	L5/S1/Right		Yes	Y	20.0	Bipolar epidural coagulation	2.815	Slit	3 to 6 mm	Tight fitting sequester	7
07/0702	HD	2015-01-20	08:58/09:53	L5/S1/Right		Yes	Y	50.0	Sponge and Bipolar epidural coagulation	2.250	Slit	3 to 6 mm	Fibrousness tissue	14
07/0703	ADD	2015-03-03	08:51/09:46	L4/L5/Right	L3/L4/Left/Right	Yes	Y	70.0	Sponge and Bipolar epidural coagulation	1.691	Slit	0 to 3 mm	Tight fitting sequester	11

Listing 16.2.1.7: Surgery and Tissue Explant - all enrolled subjects

Site/Subject ID	Type of degenerative lumbar disc	Date of procedure	Start/End Time	Location herniated disc between	Location adjacent disc between	Practicability of surgical instruments acceptable?	Use of micro-scope	Blood content (ml)	Technique haemostasis	Amount of tissue (g)	_Anulus defect_ Type	Size	Description of removed sequester	Post-operative length of hospital-ization (days)
07/0704	HD	2015-07-16	08:56/ 10:34	L4/L5/Left		Yes	Y	36.0	Sponge and Bipolar epidural coagulation	1.321	Slit	0 to 3 mm	Tight fitting sequester	5
07/0705	HD	2015-08-13	08:49/ 09:42	L5/S1/Right		Yes	Y	100.0	Bipolar epidural coagulation	-	Slit	> 6 mm	Loose sequester	-
07/0706	HD	2015-12-01	10:48/ 11:37	L3/L4/Right		Yes	Y	10.0	Sponge and Bipolar epidural coagulation	1.512	Slit	0 to 3 mm	Tight fitting sequester	10
08/0801	HD	2014-11-03	13:00/ 14:03	L4/L5/Left		Yes	Y	50.0	Sponge and Bipolar epidural coagulation	0.850	Slit	0 to 3 mm	Tight fitting sequester	4
08/0802	HD	2014-11-27	09:45/ 10:50	L3/L4/Right		Yes	Y	30.0	Bipolar epidural coagulation	0.243	Slit	0 to 3 mm	Loose sequester	7
08/0803	HD	2015-02-25	14:56/ 15:38	L5/S1/Left		Yes	Y	25.0	Sponge and Bipolar epidural coagulation	1.351	Slit	0 to 3 mm	Loose sequester	6
08/0804	HD	2015-06-03	10:40/ 11:40	L3/L4/Left		Yes	Y	240.0	Bipolar epidural coagulation	2.579	Slit	0 to 3 mm	Loose sequester	7
08/0805	HD	2015-06-25	12:38/ 14:22	L2/L3/Right		Yes	Y	500.0	Sponge and Bipolar epidural coagulation	0.613	NA	0 to 3 mm	Tight fitting sequester	6

Listing 16.2.1.7: Surgery and Tissue Explant - all enrolled subjects

Site/Subject ID	Type of degenerative lumbar disc	Date of procedure	Start/End Time	Location herniated disc between	Location adjacent disc between	Practicability of surgical instruments acceptable?	Use of micro-scope	Blood content (ml)	Technique haemostasis	Amount of tissue (g)	_Anulus defect_ Type	Size	Description of removed sequester	Post-operative length of hospitalization (days)
08/0806	HD	2015-07-08	11:18/12:18	L2/L3/Right		Yes	Y	25.0	Sponge and Bipolar epidural coagulation	1.781	Slit	0 to 3 mm	Loose sequester	5
08/0807	HD	2015-11-19	14:17/15:26	L4/L5/Right		Yes	Y	30.0	Sponge and Bipolar epidural coagulation	1.053	NA	0 to 3 mm	Compact tissue	7
08/0808	HD	2015-12-03	09:16/10:55	L3/L4/Right		Yes	Y	100.0	Bipolar epidural coagulation	1.067	Slit	0 to 3 mm	Loose sequester	6
09/0901	HD	2014-10-30	08:15/08:55	L5/S1/Right		Yes	Y	0.0	Bipolar epidural coagulation	4.330	Total defect (hole)	0 to 3 mm	Fibrousness tissue	5
09/0903	HD	2014-11-20	10:05/11:00	L3/L4/Right		Yes	Y	100.0	Sponge	0.206	Slit	3 to 6 mm	Loose sequester	8
09/0904	HD	2015-02-09	09:40/10:16	L4/L5/Left		Yes	Y	0.0	Bipolar epidural coagulation	0.787	Slit	0 to 3 mm	Compact tissue	5
09/0905	HD	2015-03-19	10:18/11:10	L4/L5/Right		Yes	Y	0.0	Sponge and Bipolar epidural coagulation	2.790	Torn	0 to 3 mm	Loose sequester	10
09/0907	HD	2015-04-15	12:03/12:41	L5/S1/Left		Yes	Y	0.0	Bipolar epidural coagulation	1.666	Slit	0 to 3 mm	Fibrousness tissue	5
09/0908	HD	2015-05-07	15:05/15:50	L4/L5/Left		Yes	Y	0.0	Bipolar epidural coagulation	1.330	Slit	0 to 3 mm	Tight fitting sequester	10

Listing 16.2.1.7: Surgery and Tissue Explant - all enrolled subjects

Site/Subject ID	Type of degenerative lumbar disc	Date of procedure	Start/End Time	Location herniated disc between	Location adjacent disc between	Practicability of surgical instruments acceptable?	Use of micro-scope	Blood content (ml)	Technique haemostasis	Amount of tissue (g)	_Anulus defect_ Type	Size	Description of removed sequester	Post-operative length of hospitalization (days)
09/0909	HD	2015-05-12	09:37/10:37	L5/S1/Left		Yes	Y	0.0	Sponge and Bipolar epidural coagulation	1.021	Slit	0 to 3 mm	Loose sequester	14
09/0910	HD	2015-09-01	12:42/13:30	L5/S1/Left		Yes	Y	0.0	Sponge and Bipolar epidural coagulation	2.512	Slit	3 to 6 mm	Tight fitting sequester, Compact tissue	12
09/0911	HD	2015-10-19	10:58/11:53	L5/S1/Right		Yes	Y	0.0	Bipolar epidural coagulation	0.403	Slit	3 to 6 mm	Compact tissue	5
09/0912	HD	2015-10-20	10:40/11:11	L5/S1/Right		Yes	Y	0.0	Bipolar epidural coagulation	5.003	Slit	3 to 6 mm	Loose sequester, Fibrousness tissue	5
09/0913	HD	2015-11-30	09:59/11:36	L4/L5/Right		Yes	Y	300.0	Sponge and Bipolar epidural coagulation	1.892	Torn	3 to 6 mm	Fibrousness tissue	7
09/0914	HD	2016-01-06	08:19/09:00	L5/S1/Left		Yes	Y	0.0	Bipolar epidural coagulation	2.306	Total defect (hole)	3 to 6 mm	Tight fitting sequester, Compact tissue	5
09/0915	HD	2016-01-06	14:28/15:39	L4/L5/Right		Yes	Y	0.0	Sponge and Bipolar epidural coagulation	2.344	Slit	3 to 6 mm	Tight fitting sequester, Compact tissue	4

Listing 16.2.1.7: Surgery and Tissue Explant - all enrolled subjects

Site/Subject ID	Type of degenerative lumbar disc	Date of procedure	Start/End Time	Location herniated disc between	Location adjacent disc between	Practicability of surgical instruments acceptable?	Use of micro-scope	Blood content (ml)	Technique haemostasis	Amount of tissue (g)	_Anulus defect_ Type	Size	Description of removed sequester	Post-operative length of hospital-ization (days)
09/0916	HD	2016-02-23	12:20/12:53	L5/S1/Right		Yes	Y	0.0	Bipolar epidural coagulation	1.141	Slit	3 to 6 mm	Compact tissue	5
11/1101	ADD	2015-01-13	08:38/09:39	L5/S1/Left	L4/L5/Left/Right	Yes	Y	50.0	Bipolar epidural coagulation	2.757	Total defect (hole)	3 to 6 mm	Loose sequester, Fibrousness tissue, Compact tissue	7
11/1102	HD	2015-04-20	14:26/15:16	L5/S1/Left		Yes	Y	100.0	Sponge and Bipolar epidural coagulation	6.820	Total defect (hole)	> 6 mm	Compact tissue	10
11/1103	HD	2015-08-03	08:17/09:34	L5/S1/Left		Yes	Y	50.0	Bipolar epidural coagulation	2.125	Total defect (hole)	3 to 6 mm	Tight fitting sequester	12
11/1104	HD	2016-03-07	12:32/13:28	L5/S1/Left		Yes	Y	60.0	Bipolar epidural coagulation	7.541	Total defect (hole)	> 6 mm	Loose sequester	5
12/1201	HD	2015-09-07	15:25/15:54	L5/S1/Right		Yes	Y	5.0	Bipolar epidural coagulation	0.729	Slit	3 to 6 mm	Loose sequester	21
13/1301	ADD	2015-04-27	08:30/10:09	L5/S1/Right	L4/L5/Right	Yes	Y	30.0	Bipolar epidural coagulation	0.837	Slit	0 to 3 mm	Loose sequester	8
13/1302	HD	2015-05-12	08:31/09:39	L4/L5/Right		Yes	Y	80.0	Bipolar epidural coagulation	3.654	Torn	0 to 3 mm	Loose sequester	12

Listing 16.2.1.7: Surgery and Tissue Explant - all enrolled subjects

Site/Subject ID	Type of degenerative lumbar disc	Date of procedure	Start/End Time	Location herniated disc between	Location adjacent disc between	Practicability of surgical instruments acceptable?	Use of micro-scope	Blood content (ml)	Technique haemostasis	Amount of tissue (g)	_Anulus defect_ Type	Size	Description of removed sequester	Post-operative length of hospitalization (days)
13/1303	HD	2015-06-29	08:28/10:01	L5/S1/Right		Yes	N	100.0	Bipolar epidural coagulation	3.678	Slit	3 to 6 mm	Loose sequester	6
13/1304	HD	2015-07-02	08:25/09:55	L5/S1/Left		Yes	N	50.0	Bipolar epidural coagulation	0.966	Torn	3 to 6 mm	Tight fitting sequester	7
13/1305	ADD	2015-10-15	08:25/09:30	L5/S1/Right	L4/L5/Right	Yes	N	25.0	Bipolar epidural coagulation	0.907	Slit	3 to 6 mm	Loose sequester, Compact tissue	9

Listing 16.2.1.8: Serology - all enrolled subjects

Site/Subject ID	Blood sample taken?	Date of collection	Visit	Result	HIV	HBs-Ag	Anti-HBc-AK	Anti-HCV	TPHA/TPPA
01/0123	Yes	16SEP2014	VISIT 2B	Positive			Yes		
	Yes	19DEC2014	VISIT 3B	Positive			Yes		
01/0124	Yes	06NOV2014	VISIT 2B	Negative					
01/0125	Yes	07OCT2014	VISIT 2B	Negative					
01/0126	Yes	08OCT2014	VISIT 2B	Negative					
	Yes	08JAN2015	VISIT 3B	Negative					
01/0127	Yes	20OCT2014	VISIT 2B	Negative					
	Yes	09JAN2015	VISIT 3B	Negative					
01/0128	Yes	21OCT2014	VISIT 2B	Negative					
	Yes	13JAN2015	VISIT 3B	Negative					
01/0129	Yes	29OCT2014	VISIT 2B	Negative					
01/0130	Yes	20NOV2014	VISIT 2B	Negative					
	Yes	03FEB2015	VISIT 3B	Negative					
01/0131	Yes	01DEC2014	VISIT 2B	Negative					
	Yes	19FEB2015	VISIT 3B	Negative					
01/0132	Yes	02DEC2014	VISIT 2B	Negative					
01/0133	Yes	16DEC2014	VISIT 2B	Negative					
01/0134	Yes	17DEC2014	VISIT 2B	Negative					
01/0135	Yes	15JAN2015	VISIT 2B	Negative					
	Yes	08APR2015	VISIT 3B	Negative					
01/0136	Yes	23FEB2015	VISIT 2B	Negative					
	Yes	02JUN2015	VISIT 3B	Negative					
01/0137		26FEB2015	VISIT 2B	Negative					
	Yes	02JUN2015	VISIT 3B	Negative					
01/0138	Yes	09MAR2015	VISIT 2B	Negative					

Listing 16.2.1.8: Serology - all enrolled subjects

Site/Subject ID	Blood sample taken?	Date of collection	Visit	Result	HIV	HBs-Ag	Anti-HBc-AK	Anti-HCV	TPHA/TPPA
01/0139	Yes	10MAR2015	VISIT 2B	Negative					
	Yes	03JUN2015	VISIT 3B	Negative					
01/0140	Yes	12MAY2015	VISIT 2B	Negative					
		11AUG2015	VISIT 3B	Negative					
01/0141	Yes	27MAY2015	VISIT 2B	Negative					
01/0142	Yes	27MAY2015	VISIT 2B	Negative					
	Yes	25AUG2015	VISIT 3B	Negative					
01/0143	Yes	17JUN2015	VISIT 2B	Negative					
	Yes	22SEP2015	VISIT 3B	Negative					
01/0144	Yes	24JUN2015	VISIT 2B	Negative					
	Yes	22SEP2015	VISIT 3B	Negative					
01/0145	Yes	16JUL2015	VISIT 2B	Negative					
	Yes	06OCT2015	VISIT 3B	Negative					
01/0146	Yes	16JUL2015	VISIT 2B	Negative					
01/0147	Yes	20AUG2015	VISIT 2B	Negative					
	Yes	18NOV2015	VISIT 3B	Negative					
01/0148	Yes	22OCT2015	VISIT 2B	Negative					
	Yes	12JAN2016	VISIT 3B	Negative					
01/0149	Yes	03DEC2015	VISIT 2B	Negative					
	Yes	01MAR2016	VISIT 3B	Negative					
01/0150	Yes	03FEB2016	VISIT 2B						
01/0151	Yes	03MAR2016	VISIT 2B	Negative					
	Yes	07JUN2016	VISIT 3B	Negative					
01/0152	Yes	03MAR2016	VISIT 2B	Negative					
01/0153	Yes	21MAR2016	VISIT 2B	Negative					
	Yes	07JUN2016	VISIT 3B	Negative					

Listing 16.2.1.8: Serology - all enrolled subjects

Site/Subject ID	Blood sample taken?	Date of collection	Visit	Result	HIV	HBs-Ag	Anti-HBc-AK	Anti-HCV	TPHA/TPPA
02/0209	Yes	23OCT2014	VISIT 2B	Negative					
	Yes	30JAN2015	VISIT 3B	Negative					
02/0210	Yes	13NOV2014	VISIT 2B						
02/0211	Yes	11DEC2014	VISIT 2B	Negative					
02/0212	Yes	16DEC2014	VISIT 2B	Negative					
02/0213	Yes	18DEC2014	VISIT 2B	Negative					
02/0214	Yes	25FEB2015	VISIT 2B	Negative					
	Yes	28MAY2015	VISIT 3B	Negative					
02/0215	No	-	VISIT 2B						
02/0216	Yes	28APR2015	VISIT 2B	Negative					
	Yes	23JUL2015	VISIT 3B	Negative					
02/0217	Yes	28MAY2015	VISIT 2B	Negative					
02/0218	Yes	30JUN2015	VISIT 2B	Negative					
02/0219	Yes	11JUN2015	VISIT 2B	Negative					
	Yes	25SEP2015	VISIT 3B	Negative					
02/0220	Yes	13AUG2015	VISIT 2B	Negative					
02/0221	Yes	01SEP2015	VISIT 2B	Negative					
02/0222	Yes	10SEP2015	VISIT 2B	Negative					
02/0223	Yes	29DEC2015	VISIT 2B	Negative					
	Yes	22MAR2016	VISIT 3B	Negative					
02/0224	Yes	29DEC2015	VISIT 2B	Negative					
04/0401	Yes	30JUN2015	VISIT 2B	Negative					
06/0604	Yes	28OCT2014	VISIT 2B	Negative					

Listing 16.2.1.8: Serology - all enrolled subjects

Site/Subject ID	Blood sample taken?	Date of collection	Visit	Result	HIV	HBs-Ag	Anti-HBc-AK	Anti-HCV	TPHA/TPPA
06/0605	Yes	11DEC2014	VISIT 2B	Negative					
06/0606	Yes	16DEC2014	VISIT 2B	Negative					
06/0607	Yes	20JAN2015	VISIT 2B	Negative					
	Yes	15APR2015	VISIT 3B	Negative					
06/0608	Yes	29JAN2015	VISIT 2B	Positive			Yes		
06/0609	Yes	16APR2015	VISIT 2B	Negative					
06/0610	Yes	25JUN2015	VISIT 2B	Negative					
	Yes	08SEP2015	VISIT 3B	Negative					
06/0611	No	15JUL2015	VISIT 2B						
06/0612	Yes	15JUL2015	VISIT 2B	Negative					
	Yes	20OCT2015	VISIT 3B	Negative					
06/0613	Yes	20JUL2015	VISIT 2B	Negative					
06/0614	Yes	17AUG2015	VISIT 2B	Negative					
	Yes	18NOV2015	VISIT 3B	Negative					
06/0615	Yes	25AUG2015	VISIT 2B	Negative					
06/0616	No	09NOV2015	VISIT 2B						
06/0617	Yes	22DEC2015	VISIT 2B	Negative					
06/0618	No	18JAN2016	VISIT 2B						
06/0619	Yes	23FEB2016	VISIT 2B	Negative					
	Yes	10MAY2016	VISIT 3B	Negative					
06/0620	Yes	24FEB2016	VISIT 2B	Negative					
07/0701	Yes	06NOV2014	VISIT 2B	Negative					
	Yes	20JAN2015	VISIT 3B	Negative					

Listing 16.2.1.8: Serology - all enrolled subjects

Site/Subject ID	Blood sample taken?	Date of collection	Visit	Result	HIV	HBs-Ag	Anti-HBc-AK	Anti-HCV	TPHA/TPPA
07/0702	Yes	20JAN2015	VISIT 2B	Positive			Yes		
07/0703	Yes	03MAR2015	VISIT 2B	Negative					
	Yes	19MAY2015	VISIT 3B	Negative					
07/0704	Yes	16JUL2015	VISIT 2B	Negative					
	Yes	08OCT2015	VISIT 3B	Negative					
07/0705	No	-	VISIT 2B						
07/0706	Yes	01DEC2015	VISIT 2B	Negative					
08/0801	Yes	03NOV2014	VISIT 2B	Negative					
08/0802	Yes	27NOV2014	VISIT 2B	Negative					
	Yes	04MAR2015	VISIT 3B	Negative					
08/0803	Yes	25FEB2015	VISIT 2B	Negative					
	Yes	16JUN2015	VISIT 3B	Negative					
08/0804	Yes	03JUN2015	VISIT 2B	Negative					
	Yes	21AUG2015	VISIT 3B	Negative					
08/0805	Yes	25JUN2015	VISIT 2B	Negative					
	Yes	22SEP2015	VISIT 3B	Negative					
08/0806	Yes	08JUL2015	VISIT 2B	Negative					
	Yes	29SEP2015	VISIT 3B	Negative					
08/0807	Yes	19NOV2015	VISIT 2B	Negative					
	Yes	02FEB2016	VISIT 3B	Negative					
08/0808	Yes	03DEC2015	VISIT 2B						
09/0901	Yes	30OCT2014	VISIT 2B	Negative					
09/0903	Yes	20NOV2014	VISIT 2B	Negative					
	No	-	VISIT 3B						
09/0904	Yes	09FEB2015	VISIT 2B	Negative					

Listing 16.2.1.8: Serology - all enrolled subjects

Site/Subject ID	Blood sample taken?	Date of collection	Visit	Result	HIV	HBs-Ag	Anti-HBc-AK	Anti-HCV	TPHA/TPPA
09/0904	Yes	21MAY2015	VISIT 3B	Negative					
09/0905	Yes	19MAR2015	VISIT 2B	Negative					
	Yes	25JUN2015	VISIT 3B	Negative					
09/0907	Yes	15APR2015	VISIT 2B	Negative					
09/0908	Yes	07MAY2015	VISIT 2B	Negative					
	Yes	06AUG2015	VISIT 3B	Negative					
09/0909	Yes	12MAY2015	VISIT 2B	Negative					
	Yes	13AUG2015	VISIT 3B	Negative					
09/0910	Yes	01SEP2015	VISIT 2B	Negative					
09/0911	Yes	19OCT2015	VISIT 2B	Negative					
	Yes	14JAN2016	VISIT 3B	Negative					
09/0912	Yes	20OCT2015	VISIT 2B	Negative					
	Yes	21JAN2016	VISIT 3B	Negative					
09/0913	Yes	30NOV2015	VISIT 2B	Negative					
	Yes	18FEB2016	VISIT 3B	Negative					
09/0914	Yes	06JAN2016	VISIT 2B	Negative					
09/0915	Yes	06JAN2016	VISIT 2B	Negative					
	Yes	23MAR2016	VISIT 3B	Negative					
09/0916	Yes	23FEB2016	VISIT 2B	Positive			Yes		
11/1101	Yes	13JAN2015	VISIT 2B	Negative					
	Yes	31MAR2015	VISIT 3B	Negative					
11/1102	Yes	20APR2015	VISIT 2B	Negative					
	Yes	28JUL2015	VISIT 3B	Negative					
11/1103	Yes	03AUG2015	VISIT 2B	Negative					
11/1104	Yes	07MAR2016	VISIT 2B	Negative					

Listing 16.2.1.8: Serology - all enrolled subjects

Site/Subject ID	Blood sample taken?	Date of collection	Visit	Result	HIV	HBs-Ag	Anti-HBc-AK	Anti-HCV	TPHA/TPPA
11/1104	Yes	07JUN2016	VISIT 3B	Positive					
12/1201	Yes	07SEP2015	VISIT 2B	Negative					
	Yes	01DEC2015	VISIT 3B	Negative					
13/1301	Yes	27APR2015	VISIT 2B	Negative					
	No	-	VISIT 3B						
13/1302	Yes	12MAY2015	VISIT 2B	Negative					
	Yes	29JUL2015	VISIT 3B						
13/1303	Yes	29JUN2015	VISIT 2B	Negative					
13/1304	Yes	02JUL2015	VISIT 2B	Negative					
	Yes	18SEP2015	VISIT 3B	Negative					
13/1305	Yes	15OCT2015	VISIT 2B	Negative					

Listing 16.2.1.9: Feasibility of transplantation - all enrolled subjects

Site/Subject ID	Treatment group	Type of degenerative lumbar disc	Date of procedure	Start/End Time	herniated disc			adjacent disc			Total Radiation Dose		Post-operative length of hospitalization (days)
					Location between	Volume (mL)	Application pressure	Location between	Volume (mL)	Application pressure	(cGy cm2)	Time (sec)	
01/0103	ND basic	HD	2013-01-15	14:00/ 14:28	L4 and L5 Right	1.1	Normal		1.1	Normal	-	-	5
01/0104	ND basic	ADD	2013-01-22	14:37/ 15:01	L5 and S1 Right	1.3	Normal	L4 and L5 Right	1.2	Normal	189.44	36	4
01/0106	ND plus	HD	2013-02-19	15:05/ 15:30	L5 and S1 Right	1.0	Normal		1.0	Normal	-	-	4
01/0107	ND plus	HD	2013-04-09	13:33/ 13:50	L4 and L5 Right	1.0	Normal		1.0	Normal	478.32	-	4
01/0108	ND plus	HD	2013-04-16	15:10/ 16:10	L5 and S1 Left	1.0	High		1.0	High	-	-	4
01/0110	ND basic	ADD	2013-04-23	13:32/ 13:50	L5 and S1 Right	1.1	Low	L4 and L5 Right	1.1	Low	538.8	-	5
01/0111	ND plus	HD	2013-06-11	13:27/ 13:43	L5 and S1 Left	1.0	High		1.0	High	195.79	24	4
01/0113	ND basic	HD	2013-08-06	15:00/ 15:17	L5 and S1 Left	1.0	High		1.0	High	305.55	36	5
01/0114	ND basic	HD	2013-09-11	13:40/ 14:00	L4 and L5 Left	1.1	Low		1.1	Low	184.25	18	4
01/0115	ND plus	HD	2013-09-17	17:05/ 17:20	L5 and S1 Left	1.1	Low		1.1	Low	142.46	18	4
01/0118	ND plus	HD	2013-10-08	14:17/ 14:45	L5 and S1 Left	1.1	High		1.1	High	995.68	54	5
01/0119	ND basic	HD	2013-10-15	14:16/ 14:45	L5 and S1 Left	1.4	High		1.4	High	888.49	80	5

Listing 16.2.1.9: Feasibility of transplantation - all enrolled subjects

Site/Subject ID	Treatment group	Type of degenerative lumbar disc	Date of procedure	Start/End Time	herniated disc			adjacent disc			Total Radiation Dose		Post-operative length of hospitalization (days)
					Location between	Volume (mL)	Application pressure	Location between	Volume (mL)	Application pressure	(cGy cm2)	Time (sec)	
01/0121	ND plus	HD	2014-01-14	15:20/ 15:35	L5 and S1 Right	1.1	Low		1.1	Low	6976	14	4
01/0122	ND plus	HD	2013-12-17	16:08/ 16:20	L5 and S1 Left	0.5	High		0.5	High	309.32	31	4
01/0123	ND plus	HD	2014-12-19	13:10/ 13:20	L4 and L5 Right	1.3	Normal		1.3	Normal	206	18	3
01/0126	ND basic	HD	2015-01-08	12:55/ 13:10	L4 and L5 Left	1.2	Normal		1.2	Normal	82.96	19	3
01/0127	ND plus	HD	2015-01-09	14:55/ 15:50	L5 and S1 Right	0.9	Normal		0.9	Normal	679.2	125	3
01/0128	ND plus	ADD	2015-01-13	14:40/ 15:15	L4 and L5 Right	1.1	High	L5 and S1 Right	1.2	Normal	0	0	4
01/0130	ND basic	HD	2015-02-03	14:35/ 14:55	L4 and L5 Left	1.3	Normal		1.3	Normal	286.48	28	3
01/0131	ND plus	HD	2015-02-19	15:35/ 15:55	L4 and L5 Right	1.2	Low		1.2	Low	147.7	18	3
01/0135	ND plus	HD	2015-04-08	14:05/ 14:25	L5 and S1 Right	0.8	High		0.8	High	716.02	91	3
01/0136	ND basic	HD	2015-06-02	13:35/ 13:50	L4 and L5 Right	0.9	High		0.9	High	166.39	29	3
01/0137	ND plus	HD	2015-06-02	12:45/ 13:00	L4 and L5 Left	1.3	Low		1.3	Low	61.28	21	3
01/0139	ND plus	HD	2015-06-03	17:05/ 17:40	L5 and S1 Right	0.9	High		0.9	High	1311.73	56	3

Listing 16.2.1.9: Feasibility of transplantation - all enrolled subjects

Site/Subject ID	Treatment group	Type of degenerative lumbar disc	Date of procedure	Start/End Time	herniated disc			adjacent disc			Total Radiation Dose		Post-operative length of hospitalization (days)
					Location between	Volume (mL)	Application pressure	Location between	Volume (mL)	Application pressure	(cGy cm2)	Time (sec)	
01/0140	ND basic	HD	2015-08-11	13:55/14:10	L5 and S1 Right	1.1	Normal		1.1	Normal	213	25	3
01/0142	ND plus	HD	2015-08-25	18:10/18:20	L5 and S1 Right	1.1	High		1.1	High	278.32	43	3
01/0143	ND plus	HD	2015-09-22	20:30/20:45	L4 and L5 Left	1.2	Normal		1.2	Normal	255.84	27	3
01/0144	ND basic	HD	2015-09-22	19:35/19:50	L5 and S1 Left	1.0	High		1.0	High	133.74	18	3
01/0145	ND plus	HD	2015-10-07	07:10/07:25	L5 and S1 Right	1.3	Normal		1.3	Normal	361.37	23	3
01/0147	ND plus	HD	2015-11-18	14:05/14:20	L4 and L5 Left	1.2	Normal		1.2	Normal	74.54	21	3
01/0148	ND plus	HD	2016-01-12	18:00/18:20	L5 and S1 Right	1.2	Normal		1.2	Normal	339.83	22	3
01/0149	ND plus	HD	2016-03-01	18:45/19:05	L4 and L5 Left	1.5	Normal		1.5	Normal	274.93	21	3
01/0151	ND basic	ADD	2016-06-07	18:00/18:25	L5 and S1 Right	1.0	High	L4 and L5 Right	1.0	High	-	-	3
01/0153	ND basic	ADD	2016-06-07	19:05/19:30	L5 and S1 Right	1.2	Normal	L4 and L5 Right	1.1	High	-	-	3
02/0201	ND plus	ADD	2013-05-07	13:30/14:00	L4 and L5 Left	1.0	Normal	L5 and S1 UNK	0.5	Normal	-	-	3
02/0203	ND basic	ADD	2013-06-26	11:35/11:50	L4 and L5 Left	1.2	Normal	L3 and L4 UNK	1.2	Normal	-	-	4

Listing 16.2.1.9: Feasibility of transplantation - all enrolled subjects

Site/Subject ID	Treatment group	Type of degenerative lumbar disc	Date of procedure	Start/End Time	herniated disc			adjacent disc			Total Radiation Dose		Post-operative length of hospitalization (days)
					Location between	Volume (mL)	Application pressure	Location between	Volume (mL)	Application pressure	(cGy cm2)	Time (sec)	
02/0205	ND basic	HD	2013-07-31	12:45/13:55	L5 and S1 Left	1.8	Normal		1.8	Normal	-	-	4
02/0206	ND plus	HD	2013-10-08	12:35/12:50	L4 and L5 Left	1.5	Normal		1.5	Normal	222.11	19	4
02/0208	ND plus	ADD	2013-12-10	14:04/14:20	L5 and S1 Left	2.0	Normal	L4 and L5 Left/Right	2.0	Normal	-	-	4
02/0209	ND plus	HD	2015-01-30	17:21/17:35	L4 and L5 Right	1.0	Normal		1.0	Normal	-	-	3
02/0214	ND plus	HD	2015-05-28	12:40/12:55	L4 and L5 Right	1.5	Normal		1.5	Normal	100.3	13	3
02/0216	ND plus	ADD	2015-07-23	14:20/14:55	L5 and S1 Left	1.0	Normal		1.0	Normal	-	-	3
02/0219	ND basic	HD	2015-09-25	11:50/12:00	L5 and S1 Left	1.2	Normal		1.2	Normal	157.96	15	3
02/0223	ND basic	HD	2016-03-22	14:05/14:25	L5 and S1 Left	1.0	UNK		1.0	UNK	205.47	39	3
06/0602	ND plus	HD	2013-11-05	10:54/11:16	L3 and L4 Left	1.5	Normal		1.5	Normal	574.97	57	4
06/0607	ND plus	HD	2015-04-15	11:48/12:11	L5 and S1 Right	1.5	High		1.5	High	477.3	53	3
06/0610	ND plus	ADD	2015-09-08	12:37/13:46	L5 and S1 Left	2.0	Normal	L4 and L5 Left	2.3	Normal	151.45	13	3
06/0612	ND plus	HD	2015-10-20	11:56/12:11	L4 and L5 Left	2.5	Low		2.5	Low	156.18	25	3

Listing 16.2.1.9: Feasibility of transplantation - all enrolled subjects

Site/Subject ID	Treatment group	Type of degenerative lumbar disc	Date of procedure	Start/End Time	herniated disc			adjacent disc			_Total Radiation Dose (cGy cm2)	Time (sec)	Post-operative length of hospitalization (days)
					Location between	Volume (mL)	Application pressure	Location between	Volume (mL)	Application pressure			
06/0614	ND plus	ADD	2015-11-18	13:29/13:55	L5 and S1 Right	2.0	High	L4 and L5 Right	1.5	High	121.69	30	1
06/0619	ND basic	HD	2016-05-10	10:00/10:37	L4 and L5 Right	1.3	Normal		1.3	Normal	656.3	58	2
07/0701	ND plus	HD	2015-01-20	10:54/11:15	L5 and S1 Right	1.2	Normal		1.2	Normal	146.61	18	3
07/0703	ND plus	ADD	2015-05-19	13:23/13:45	L4 and L5 Right	1.0	Low	L3 and L4 Left/Right	1.0	Low	-	-	3
07/0704	ND basic	HD	2015-10-08	11:37/11:48	L4 and L5 Left	1.0	Normal		1.0	Normal	428.95	33	2
08/0802	ND plus	HD	2015-03-04	13:33/13:45	L3 and L4 Right	2.5	Normal		2.5	Normal	120.8	25	3
08/0803	ND basic	HD	2015-06-16	13:01/13:29	L5 and S1 Left	1.8	Normal		1.8	Normal	272.2	38	2
08/0804	ND plus	HD	2015-08-21	15:20/15:40	L3 and L4 Left	1.5	Low		1.5	Low	243.67	37	2
08/0805	ND basic	HD	2015-09-22	14:33/14:52	L2 and L3 Right	1.5	Low		1.5	Low	542.25	53	3
08/0806	ND plus	HD	2015-09-29	18:02/18:20	L2 and L3 Right	1.8	Low		1.8	Low	221.7	32	2
08/0807	ND plus	HD	2016-02-02	18:19/18:35	L4 and L5 Right	1.0	High		1.0	High	138.26	24	3
09/0904	ND basic	HD	2015-05-21	11:00/11:28	L4 and L5 Left	1.4	Normal		1.4	Normal	423.4	38	2

Listing 16.2.1.9: Feasibility of transplantation - all enrolled subjects

Site/Subject ID	Treatment group	Type of degenerative lumbar disc	Date of procedure	Start/End Time	herniated disc			adjacent disc			Total Radiation Dose		Post-operative length of hospitalization (days)
					Location between	Volume (mL)	Application pressure	Location between	Volume (mL)	Application pressure	(cGy cm2)	Time (sec)	
09/0905	ND plus	HD	2015-06-25	10:48/11:41	L4 and L5 Right	1.8	Normal		1.8	Normal	300.1	39	2
09/0908	ND basic	HD	2015-08-06	10:26/10:44	L4 and L5 Left	2.0	Normal		2.0	Normal	150.7	23	2
09/0909	ND plus	HD	2015-08-13	11:42/11:59	L5 and S1 Left	1.7	High		1.7	High	208.6	21	2
09/0911	ND plus	HD	2016-01-14	09:36/09:56	L5 and S1 Right	2.2	Normal		2.2	Normal	203.6	21	2
09/0912	ND plus	HD	2016-01-21	15:46/16:09	L5 and S1 Right	2.0	Normal		2.0	Normal	443.6	44	3
09/0913	ND basic	HD	2016-02-18	12:29/12:43	L4 and L5 Right	2.1	High		2.1	High	239.2	21	2
09/0915	ND basic	HD	2016-03-24	13:37/13:53	L4 and L5 Right	2.0	Normal		2.0	Normal	95.5	8	1
11/1101	ND plus	ADD	2015-03-31	14:12/14:38	L5 and S1 Left	1.3	Low	L4 and L5	1.0	Normal	-	-	2
11/1102	ND basic	HD	2015-07-28	15:00/15:37	L5 and S1 Left	0.0			0.0		-	182	1
11/1104	ND plus	HD	2016-06-08	08:28/08:40	L5 and S1 Left	2.5	Normal		2.5	Normal	145.3	39	-
12/1201	ND plus	HD	2015-12-01	14:47/15:13	L5 and S1 Right	1.5	Normal		1.5	Normal	178.12	38	6
13/1301	ND plus	ADD	2015-07-29	14:33/14:58	L5 and S1 Right	1.5	Normal	L4 and L5 Right	1.5	Normal	80	7	3

Listing 16.2.1.9: Feasibility of transplantation - all enrolled subjects

Site/Subject ID	Treatment group	Type of degenerative lumbar disc	Date of procedure	Start/End Time	herniated disc			adjacent disc			Total Radiation Dose		Post-operative length of hospitalization
					Location between	Volume (mL)	Application pressure	Location between	Volume (mL)	Application pressure	(cGy cm2)	Time (sec)	
13/1302	ND plus	HD	2015-07-29	14:45/ 15:03	L4 and L5 Right	1.5	Normal		1.5	Normal	-	6	3
13/1304	ND basic	HD	2015-09-18	08:15/ 08:46	L5 and S1 Left	1.5	Normal		1.5	Normal	-	30	4

Listing 16.2.1.10: Wound assessment - all enrolled subjects

Site/Subject ID	Treatment group	Visit	Delay of wound healing?	If YES: Specify
01/0103	ND basic	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0104	ND basic	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0106	ND plus	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0107	ND plus	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0108	ND plus	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0110	ND basic	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	
		VISIT 4	No	
		VISIT 5	No	

Listing 16.2.1.10: Wound assessment - all enrolled subjects

Site/Subject ID	Treatment group	Visit	Delay of wound healing?	If YES: Specify
01/0110	ND basic	VISIT 6	No	
01/0111	ND plus	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0113	ND basic	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0114	ND basic	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0115	ND plus	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0118	ND plus	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0119	ND basic	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	

Listing 16.2.1.10: Wound assessment - all enrolled subjects

Site/Subject ID	Treatment group	Visit	Delay of wound healing?	If YES: Specify
01/0119	ND basic	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0121	ND plus	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0122	ND plus	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0123	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0125	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0126	ND basic	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0127	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0128	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	

Listing 16.2.1.10: Wound assessment - all enrolled subjects

Site/Subject ID	Treatment group	Visit	Delay of wound healing?	If YES: Specify
01/0128	ND plus	VISIT 6	No	
01/0129	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0130	ND basic	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0131	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0132	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0135	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0136	ND basic	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0137	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0138	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0139	ND plus	VISIT 3A	No	

Listing 16.2.1.10: Wound assessment - all enrolled subjects

Site/Subject ID	Treatment group	Visit	Delay of wound healing?	If YES: Specify
01/0139	ND plus	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0140	ND basic	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0141	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0142	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0143	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0144	ND basic	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0145	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0146	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0147	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	

Listing 16.2.1.10: Wound assessment - all enrolled subjects

Site/Subject ID	Treatment group	Visit	Delay of wound healing?	If YES: Specify
01/0147	ND plus	VISIT 6	No	
01/0148	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0149	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0151	ND basic	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0152	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
01/0153	ND basic	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
02/0201	ND plus	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
02/0203	ND basic	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	

Listing 16.2.1.10: Wound assessment - all enrolled subjects

Site/Subject ID	Treatment group	Visit	Delay of wound healing?	If YES: Specify
02/0205	ND basic	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
02/0206	ND plus	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
02/0208	ND plus	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 3L	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
02/0209	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
02/0211	ND basic	VISIT 3A	No	
02/0212	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
02/0214	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 6	No	
02/0216	ND plus	VISIT 3A	No	
		VISIT 5	No	
02/0217	SC	VISIT 4	No	

Listing 16.2.1.10: Wound assessment - all enrolled subjects

Site/Subject ID	Treatment group	Visit	Delay of wound healing?	If YES: Specify
02/0217	SC	VISIT 5	No	
		VISIT 6	No	
02/0219	ND basic	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
02/0220	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
02/0221	ND plus	VISIT 3A	No	
02/0223	ND basic	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
04/0401	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
06/0602	ND plus	VISIT 3A	No	
		VISIT 3K	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
06/0606	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
06/0607	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
06/0610	ND plus	VISIT 3A	No	
		VISIT 4	No	

Listing 16.2.1.10: Wound assessment - all enrolled subjects

Site/Subject ID	Treatment group	Visit	Delay of wound healing?	If YES: Specify
06/0610	ND plus	VISIT 5 VISIT 6	No No	
06/0612	ND plus	VISIT 3A VISIT 4 VISIT 5 VISIT 6	No No No No	
06/0613	SC	VISIT 4 VISIT 5 VISIT 6	No No No	
06/0614	ND plus	VISIT 3A VISIT 4 VISIT 5 VISIT 6	No No No No	
06/0617	ND plus	VISIT 3A	No	
06/0619	ND basic	VISIT 3A VISIT 4 VISIT 5 VISIT 6	No No No No	
06/0620	SC	VISIT 4 VISIT 5 VISIT 6	No No No	
07/0701	ND plus	VISIT 3A VISIT 4 VISIT 5 VISIT 6	No No No No	
07/0702	SC	VISIT 4 VISIT 5 VISIT 6	No No No	
07/0703	ND plus	VISIT 3A VISIT 4 VISIT 5	No No No	

Listing 16.2.1.10: Wound assessment - all enrolled subjects

Site/Subject ID	Treatment group	Visit	Delay of wound healing?	If YES: Specify
07/0703	ND plus	VISIT 6	No	
07/0704	ND basic	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
07/0706	SC	VISIT 4	No	
08/0801	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
08/0802	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
08/0803	ND basic	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
08/0804	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
08/0805	ND basic	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
08/0806	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
08/0807	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	

Listing 16.2.1.10: Wound assessment - all enrolled subjects

Site/Subject ID	Treatment group	Visit	Delay of wound healing?	If YES: Specify
08/0807	ND plus	VISIT 6	No	
08/0808	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
09/0901	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
09/0903	ND plus	VISIT 3A	No	
09/0904	ND basic	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
09/0905	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
09/0907	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
09/0908	ND basic	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
09/0909	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
09/0911	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	

Listing 16.2.1.10: Wound assessment - all enrolled subjects

Site/Subject ID	Treatment group	Visit	Delay of wound healing?	If YES: Specify
09/0912	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
09/0913	ND basic	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
09/0914	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
09/0915	ND basic	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
09/0916	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
11/1101	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
11/1102	ND basic	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
11/1103	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
11/1104	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	

Listing 16.2.1.10: Wound assessment - all enrolled subjects

Site/Subject ID	Treatment group	Visit	Delay of wound healing?	If YES: Specify
11/1104	ND plus	VISIT 6	No	
12/1201	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
13/1301	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
13/1302	ND plus	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
13/1303	SC	VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	
13/1304	ND basic	VISIT 3A	No	
		VISIT 4	No	
		VISIT 5	No	
		VISIT 6	No	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0103	ND basic	18OCT2012	15JAN2013	Deflamat	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain	3-4 x 100 mg if needed	2009		Yes	
		18OCT2012	15JAN2013	Deflamat	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain	3-4 x 100 mg if needed	2009		Yes	
		18OCT2012	15JAN2013	Deflamat	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain	3-4 x 100 mg if needed	2009		Yes	
		18OCT2012	15JAN2013	Deflamat	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	3-4 x 100 mg if needed	2009		Yes	
		18OCT2012	15JAN2013	Deflamat	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	3-4 x 100 mg if needed	2009		Yes	
		18OCT2012	15JAN2013	Deflamat	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain	3-4 x 100 mg if needed	2009		Yes	
		18OCT2012	15JAN2013	Dilatrend	CARVEDILOL	BETA BLOCKING AGENTS	Hypertension	37.5 mg	25Mar2013	16Apr2013		
		18OCT2012	15JAN2013	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain -other Contr. thoracis dexter	1800 mg if needed	05Dec2016	23Dec2016		
		18OCT2012	15JAN2013	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain -other Contr. thoracis dexter	1800 mg if needed	05Dec2016	23Dec2016		
		18OCT2012	15JAN2013	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain -other Contr. thoracis dexter	1800 mg if needed	05Dec2016	23Dec2016		
		18OCT2012	15JAN2013	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain -other Contr. thoracis dexter	1800 mg if needed	05Dec2016	23Dec2016		
		18OCT2012	15JAN2013	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain -other Contr. thoracis dexter	1800 mg if needed	05Dec2016	23Dec2016		
		18OCT2012	15JAN2013	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Prophylaxis	1 x 40 mg as needed	18Oct2012		Yes	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0103	ND basic	18OCT2012	15JAN2013	Amlodipin	AMLODIPINE	CALCIUM CHANNEL BLOCKERS	Hypertension	10 mg	25Mar2013		Yes	
		18OCT2012	15JAN2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombose prophylaxis	1 x 40 mg sc	17Oct2012	21Oct2012		
		18OCT2012	15JAN2013	Lendorm	BROTIZOLAM	PSYCHOLEPTICS	for sleeping	1 x 0.25 mg night	20Oct2012	20Oct2012		
		18OCT2012	15JAN2013	Baneocin	OPHTHALMO-FRAMY KOIN	THROAT PREPARATIONS	Infection prophylaxis	100 ml	18Oct2012	18Oct2012		
		18OCT2012	15JAN2013	Baneocin	OPHTHALMO-FRAMY KOIN	OPHTHALMOLOGICA LS	Infection prophylaxis	100 ml	18Oct2012	18Oct2012		
		18OCT2012	15JAN2013	Baneocin	OPHTHALMO-FRAMY KOIN	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Infection prophylaxis	100 ml	18Oct2012	18Oct2012		
		18OCT2012	15JAN2013	Candesartan HCT	BLOPRESS PLUS	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Hypertension	24 mg	Dec2012		Yes	
		18OCT2012	15JAN2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombose prophylaxis	40 mg	14Jan2013	17Jan2013		
01/0104	ND basic	18OCT2012	15JAN2013	Myolastan	TETRAZEPAM	MUSCLE RELAXANTS	Musclerelaxant	2 x 50 mg	04Feb2013	31Jul2013		
		24OCT2012	22JAN2013	Diclobene	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain medication	150 mg iv	15Oct2012	15Oct2012		
		24OCT2012	22JAN2013	Diclobene	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain medication	150 mg iv	15Oct2012	15Oct2012		
		24OCT2012	22JAN2013	Diclobene	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain medication	150 mg iv	15Oct2012	15Oct2012		
		24OCT2012	22JAN2013	Diclobene	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain medication	150 mg iv	15Oct2012	15Oct2012		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0104	ND basic	24OCT2012	22JAN2013	Dicloebene	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain medication	150 mg iv	15Oct2012	15Oct2012		
		24OCT2012	22JAN2013	Dicloebene	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain medication	150 mg iv	15Oct2012	15Oct2012		
		24OCT2012	22JAN2013	Lendorm	BROTIZOLAM	PSYCHOLEPTICS	sleep inducing	0.25 mg po	26Oct2012	26Oct2012		
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: bact. Infection	UNK	14Dec2014	19Dec2014		
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	VASOPROTECTIVES	Other: bact. Infection	UNK	14Dec2014	19Dec2014		
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	THROAT PREPARATIONS	Other: bact. Infection	UNK	14Dec2014	19Dec2014		
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	OPHTHALMOLOGICA LS	Other: bact. Infection	UNK	14Dec2014	19Dec2014		
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	ANTIFUNGALS FOR DERMATOLOGICAL USE	Other: bact. Infection	UNK	14Dec2014	19Dec2014		
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: bact. Infection	UNK	14Dec2014	19Dec2014		
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: bact. Infection	UNK	14Dec2014	19Dec2014		
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	ANTIBACTERIALS FOR SYSTEMIC USE	Other: bact. Infection	UNK	14Dec2014	19Dec2014		
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	ANTIMYCOBACTERI ALS	Other: bact. Infection	UNK	14Dec2014	19Dec2014		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0104	ND basic	24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	ANTIMYCOTICS FOR SYSTEMIC USE	Other: bact. Infection	UNK	14Dec2014	19Dec2014	
		24OCT2012	22JAN2013	Myolastan	TETRAZEPAM	MUSCLE RELAXANTS	muscle relaxant	50 mg iv	15Oct2012	15Oct2012	
		24OCT2012	22JAN2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombo-Prophyl axis	40 mg s.c.	25Oct2012	26Oct2012	
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	ANTIMYCOBACTERI ALS	Other: bact. Infection	UNK	12Jun2015	19Jun2015	
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	ANTIMYCOTICS FOR SYSTEMIC USE	Other: bact. Infection	UNK	12Jun2015	19Jun2015	
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	ANTIBACTERIALS FOR SYSTEMIC USE	Other: bact. Infection	UNK	12Jun2015	19Jun2015	
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: bact. Infection	UNK	12Jun2015	19Jun2015	
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	ANTIFUNGALS FOR DERMATOLOGICAL USE	Other: bact. Infection	UNK	12Jun2015	19Jun2015	
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: bact. Infection	UNK	12Jun2015	19Jun2015	
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	OPHTHALMOLOGICA LS	Other: bact. Infection	UNK	12Jun2015	19Jun2015	
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	THROAT PREPARATIONS	Other: bact. Infection	UNK	12Jun2015	19Jun2015	
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	VASOPROTECTIVES	Other: bact. Infection	UNK	12Jun2015	19Jun2015	
		24OCT2012	22JAN2013	ANTIBIOTICS (unknown)	ANTIBIOTICS (90046601001)	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: bact. Infection	UNK	12Jun2015	19Jun2015	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0104	ND basic	24OCT2012	22JAN2013	Ulcusan (Famotidin)	FAMOTIDINE	DRUGS FOR ACID RELATED DISORDERS	gastric protection	20 mg iv	15Oct2012	15Oct2012		
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	anti-inflammato ry	32 mg po	03Nov2012	06Nov2012		
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	anti-inflammato ry	32 mg po	03Nov2012	06Nov2012		
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	anti-inflammato ry	32 mg po	03Nov2012	06Nov2012		
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	anti-inflammato ry	32 mg po	03Nov2012	06Nov2012		
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	OTOLOGICALS	anti-inflammato ry	32 mg po	03Nov2012	06Nov2012		
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	anti-inflammato ry	32 mg po	03Nov2012	06Nov2012		
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	anti-inflammato ry	32 mg po	03Nov2012	06Nov2012		
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	anti-inflammato ry	32 mg po	03Nov2012	06Nov2012		
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	anti-inflammato ry	32 mg po	03Nov2012	06Nov2012		
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	anti-inflammato ry	32 mg po	03Nov2012	06Nov2012		
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	anti-inflammato ry	32 mg po	03Nov2012	06Nov2012		
		24OCT2012	22JAN2013	Diclovene	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	pain medication	200 mg po	16Oct2012	22Oct2012		
		24OCT2012	22JAN2013	Diclovene	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	pain medication	200 mg po	16Oct2012	22Oct2012		
		24OCT2012	22JAN2013	Diclovene	DICLOFENAC SODIUM	THROAT PREPARATIONS	pain medication	200 mg po	16Oct2012	22Oct2012		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0104	ND basic	24OCT2012	22JAN2013	Diclovene	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	pain medication	200 mg po	16Oct2012	22Oct2012	
		24OCT2012	22JAN2013	Diclovene	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	pain medication	200 mg po	16Oct2012	22Oct2012	
		24OCT2012	22JAN2013	Diclovene	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	pain medication	200 mg po	16Oct2012	22Oct2012	
		24OCT2012	22JAN2013	Clavanox	SPEKTRAMOX	ANTIBACTERIALS FOR SYSTEMIC USE	Lymphangitis	1 g po	15Dec2012	25Dec2012	
		24OCT2012	22JAN2013	Myolastan	TETRAZEPAM	MUSCLE RELAXANTS	muscle relaxant	50 mg po if needed	16Oct2012	31Jul2013	
		24OCT2012	22JAN2013	Betaisodona Wound Gaze	POVIDONE-IODINE	ANTISEPTICS AND DISINFECTANTS	burn wound	300 mg	10Dec2012	13Dec2012	
		24OCT2012	22JAN2013	Betaisodona Wound Gaze	POVIDONE-IODINE	MEDICATED DRESSINGS	burn wound	300 mg	10Dec2012	13Dec2012	
		24OCT2012	22JAN2013	Betaisodona Wound Gaze	POVIDONE-IODINE	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	burn wound	300 mg	10Dec2012	13Dec2012	
		24OCT2012	22JAN2013	Betaisodona Wound Gaze	POVIDONE-IODINE	OTHER DERMATOLOGICAL PREPARATIONS	burn wound	300 mg	10Dec2012	13Dec2012	
		24OCT2012	22JAN2013	Betaisodona Wound Gaze	POVIDONE-IODINE	OPHTHALMOLOGICA LS	burn wound	300 mg	10Dec2012	13Dec2012	
		24OCT2012	22JAN2013	Betaisodona Wound Gaze	POVIDONE-IODINE	THROAT PREPARATIONS	burn wound	300 mg	10Dec2012	13Dec2012	
		24OCT2012	22JAN2013	Betaisodona Wound Gaze	POVIDONE-IODINE	STOMATOLOGICAL PREPARATIONS	burn wound	300 mg	10Dec2012	13Dec2012	
		24OCT2012	22JAN2013	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	gastric protection	40 mg po	16Oct2012	29Oct2012	
		24OCT2012	22JAN2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombose prophylaxe	40 mg sc	23Jan2013	23Jan2013	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0104	ND basic	24OCT2012	22JAN2013	Baneocin	OPHTHALMO-FRAMY KOIN	THROAT PREPARATIONS	infection prophylaxis	100 ml	24Oct2012	24Oct2012	
		24OCT2012	22JAN2013	Baneocin	OPHTHALMO-FRAMY KOIN	OPHTHALMOLOGICA LS	infection prophylaxis	100 ml	24Oct2012	24Oct2012	
		24OCT2012	22JAN2013	Baneocin	OPHTHALMO-FRAMY KOIN	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	infection prophylaxis	100 ml	24Oct2012	24Oct2012	
		24OCT2012	22JAN2013	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	gastric protection	40 mg if needed	25May2013	02Jan2014	
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS / DERMATOLOGICAL PREPARATIONS	anti-inflammato ry	12 mg po	25Oct2012	27Oct2012	
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	anti-inflammato ry	12 mg po	25Oct2012	27Oct2012	
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	anti-inflammato ry	12 mg po	25Oct2012	27Oct2012	
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	anti-inflammato ry	12 mg po	25Oct2012	27Oct2012	
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	anti-inflammato ry	12 mg po	25Oct2012	27Oct2012	
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	OTOLOGICALS	anti-inflammato ry	12 mg po	25Oct2012	27Oct2012	
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	anti-inflammato ry	12 mg po	25Oct2012	27Oct2012	
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	anti-inflammato ry	12 mg po	25Oct2012	27Oct2012	
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	anti-inflammato ry	12 mg po	25Oct2012	27Oct2012	
		24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	anti-inflammato ry	12 mg po	25Oct2012	27Oct2012	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0104	ND basic	24OCT2012	22JAN2013	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	anti-inflammato ry	12 mg po	25Oct2012	27Oct2012		
01/0106	ND plus	28NOV2012	19FEB2013	Symbicort	BUDESONIDE W/FORMOTEROL FUMARATE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Asthma	320 ug	2003		Yes	
		28NOV2012	19FEB2013	Cithromax	AZITHROMYCIN	OPHTHALMOLOGICA LS	Common cold	500 mg	17Jan2014	20Jan2014		
		28NOV2012	19FEB2013	Cithromax	AZITHROMYCIN	ANTIBACTERIALS FOR SYSTEMIC USE	Common cold	500 mg	17Jan2014	20Jan2014		
		28NOV2012	19FEB2013	Cithromax	AZITHROMYCIN	ANTI-ACNE PREPARATIONS	Common cold	500 mg	17Jan2014	20Jan2014		
		28NOV2012	19FEB2013	Madopar	MADOPAR	ANTI-PARKINSON DRUGS	Other: Parkinson	200 mg/50 mg	03May2016		Yes	
		28NOV2012	19FEB2013	Xyzall	LEVOCETIRIZINE DIHYDROCHLORIDE	ANTIHISTAMINES FOR SYSTEMIC USE	anti allergic	5 mg if needed	2000		Yes	
		28NOV2012	19FEB2013	Proxen (Naproxen)	NAPROXEN	OTHER GYNECOLOGICALS	Common cold	500 mg x 1	01Apr2013	02Apr2013		
		28NOV2012	19FEB2013	Proxen (Naproxen)	NAPROXEN	ANTIINFLAMMATO RY AND ANTIRHEUMATIC PRODUCTS	Common cold	500 mg x 1	01Apr2013	02Apr2013		
		28NOV2012	19FEB2013	Proxen (Naproxen)	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Common cold	500 mg x 1	01Apr2013	02Apr2013		
		28NOV2012	19FEB2013	Proxen (Naproxen)	NAPROXEN	OPHTHALMOLOGICA LS	Common cold	500 mg x 1	01Apr2013	02Apr2013		
		28NOV2012	19FEB2013	Proxen (Naproxen)	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Common cold	500 mg x 1	01Apr2013	02Apr2013		
		28NOV2012	19FEB2013	Requip Modutab	ROPINIROLE HYDROCHLORIDE	ANTI-PARKINSON DRUGS	Other: Parkinson	8 mg	03May2016		Yes	
		28NOV2012	19FEB2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	antithrombotic- prophylaxis	40 mg 1x	29Nov2012	01Dec2012		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0106	ND plus	28NOV2012	19FEB2013	Sertraline	SERTRALINE	PSYCHOANALEPTIC S	Other: Depression/Parkinson	50 mg	03May2016		Yes	
		28NOV2012	19FEB2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Incarceration of the right knee	40 mg 1x	04Feb2013	04Feb2013		
		28NOV2012	19FEB2013	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Ulcer prophylaxis	40 mg 1x	29Nov2012	02Dec2012		
		28NOV2012	19FEB2013	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Ulcer prophylaxis	40 mg 1x	19Feb2013	20Feb2013		
		28NOV2012	19FEB2013	Cefurexim	CEFUROXIME	OPHTHALMOLOGICA LS	Infection prophylaxis surgery	1500 mg 1x	28Nov2012	28Nov2012		
		28NOV2012	19FEB2013	Cefurexim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Infection prophylaxis surgery	1500 mg 1x	28Nov2012	28Nov2012		
		28NOV2012	19FEB2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	anti thrombotic prophylaxis	40 mg 1x	18Feb2013	19Feb2013		
01/0107	ND plus	09JAN2013	09APR2013	Euthyrox	LEVOTHYROXINE SODIUM	THYROID THERAPY	substantiale Hypothyroidism	125 ul 1x	Jan2009		Yes	
		09JAN2013	09APR2013	Lendrom	BROTIZOLAM	PSYCHOLEPTICS	Sleep inducing (prophylactic)	0.25 mg 1x if needed	09Jan2013	13Jan2013		
		09JAN2013	09APR2013	Bucain 0.25 % INFILTRATION	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain - other	1 ml	20Oct2017	20Oct2017		
		09JAN2013	09APR2013	Bucain 0.25 % INFILTRATION	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain - other	1 ml	20Oct2017	20Oct2017		
		09JAN2013	09APR2013	Nebilan	NEBIVOLOL HYDROCHLORIDE	BETA BLOCKING AGENTS	Hypertension	5 mg 1x	Jan2013		Yes	
		09JAN2013	09APR2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	thrombo-prophyl axis	40 mg 1x	10Jan2013	14Jan2013		
		09JAN2013	09APR2013	VOLON (Triamcinolon) A INFILTRATION	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain - other	40 mg	20Oct2017	20Oct2017		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0107	ND plus	09JAN2013	09APR2013	VOLON (Triamcinolon) A INFILTRATION	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain - other	40 mg	20Oct2017	20Oct2017		
		09JAN2013	09APR2013	VOLON (Triamcinolon) A INFILTRATION	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain - other	40 mg	20Oct2017	20Oct2017		
		09JAN2013	09APR2013	VOLON (Triamcinolon) A INFILTRATION	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICA LS	Pain - other	40 mg	20Oct2017	20Oct2017		
		09JAN2013	09APR2013	VOLON (Triamcinolon) A INFILTRATION	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Pain - other	40 mg	20Oct2017	20Oct2017		
		09JAN2013	09APR2013	VOLON (Triamcinolon) A INFILTRATION	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Pain - other	40 mg	20Oct2017	20Oct2017		
		09JAN2013	09APR2013	VOLON (Triamcinolon) A INFILTRATION	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Pain - other	40 mg	20Oct2017	20Oct2017		
		09JAN2013	09APR2013	Mexalen	PARACETAMOL	ANALGESICS	Pain	3 g	24Dec2012	09Jan2013		
		09JAN2013	09APR2013	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Ulcer prophylaxis	40 mg 1x	10Apr2013	11Apr2013		
		09JAN2013	09APR2013	Bucain 0.25 % INFILTRATION	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain - other	1 ml	07Dec2017	07Dec2017		
		09JAN2013	09APR2013	Bucain 0.25 % INFILTRATION	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain - other	1 ml	07Dec2017	07Dec2017		
		09JAN2013	09APR2013	Atorvastatin	ATORVASTATIN	LIPID MODIFYING AGENTS	Hypercholesteri nämia	40 mg 1x	08Mar2013		Yes	
		09JAN2013	09APR2013	Lendorm	BROTIZOLAM	PSYCHOLEPTICS	sleep inducing	0.25 mg 1x	10Apr2013	10Apr2013		
		09JAN2013	09APR2013	VOLON (Triamcinolon) A INFILTRATON	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain - other	40 mg	07Dec2017	07Dec2017		
		09JAN2013	09APR2013	VOLON (Triamcinolon) A INFILTRATON	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain - other	40 mg	07Dec2017	07Dec2017		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0107	ND plus	09JAN2013	09APR2013	VOLON (Triamcinolon) A INFILTRATON	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICA LS	Pain - other	40 mg	07Dec2017	07Dec2017		
		09JAN2013	09APR2013	VOLON (Triamcinolon) A INFILTRATON	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain - other	40 mg	07Dec2017	07Dec2017		
		09JAN2013	09APR2013	VOLON (Triamcinolon) A INFILTRATON	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Pain - other	40 mg	07Dec2017	07Dec2017		
		09JAN2013	09APR2013	VOLON (Triamcinolon) A INFILTRATON	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Pain - other	40 mg	07Dec2017	07Dec2017		
		09JAN2013	09APR2013	VOLON (Triamcinolon) A INFILTRATON	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Pain - other	40 mg	07Dec2017	07Dec2017		
		09JAN2013	09APR2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	thrombo-prophyl axis	40 mg 1x	08Apr2013	11Apr2013		
		09JAN2013	09APR2013	Pramipexol Actavis	PRAMIPEXOLE DIHYDROCHLORIDE	ANTI-PARKINSON DRUGS	insomnia	0.088 mg evening	15Apr2013		Yes	
		09JAN2013	09APR2013	Cefurexim	CEFUROXIME	OPHTHALMOLOGICA LS	Infection-proph ylaxis surgery	1500 mg 1x	09Jan2013	09Jan2013		
		09JAN2013	09APR2013	Cefurexim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Infection-proph ylaxis surgery	1500 mg 1x	09Jan2013	09Jan2013		
		09JAN2013	09APR2013	Trittico ret.	TRAZODONE HYDROCHLORIDE	PSYCHOANALEPTIC S	insomnia	50 mg evening	15Apr2013		Yes	
		09JAN2013	09APR2013	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Ulcer Prophylaxis	40 mg 1x	10Jan2013	15Jan2013		
01/0108	ND plus	10JAN2013	16APR2013	Cefuroxim	METOCLOPRAMIDE HYDROCHLORIDE	DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	Nausea	10 mg 1x	14Jan2013	14Jan2013		
01/0108	ND plus	10JAN2013	16APR2013	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	infection prophylaxis surgery	1500 mg x1	10Jan2013	10Jan2013		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0108	ND plus	10JAN2013	16APR2013	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	infection prophylaxis surgery	1500 mg x1	10Jan2013	10Jan2013		
		10JAN2013	16APR2013	Mexalen (Paracetamol)	PARACETAMOL	ANALGESICS	Other: Common Cold	1500	01Jan2018	07Jan2018		
		10JAN2013	16APR2013	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	ulcer prophylaxis	40 mg x1	10Jan2013	13Jan2013		
		10JAN2013	16APR2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	thrombo prophylaxis	40 mg x1	09Jan2013	13Jan2013		
		10JAN2013	16APR2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	thrombo prophylaxis	40 mg x1	17Apr2013	17Apr2013		
01/0110	ND basic	24JAN2013	23APR2013	Proxen (Naproxen)	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Pain	1000 mg	29Dec2012	14Jan2013		
		24JAN2013	23APR2013	Proxen (Naproxen)	NAPROXEN	OPHTHALMOLOGICA LS	Pain	1000 mg	29Dec2012	14Jan2013		
		24JAN2013	23APR2013	Proxen (Naproxen)	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1000 mg	29Dec2012	14Jan2013		
		24JAN2013	23APR2013	Proxen (Naproxen)	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1000 mg	29Dec2012	14Jan2013		
		24JAN2013	23APR2013	Proxen (Naproxen)	NAPROXEN	OTHER GYNECOLOGICALS	Pain	1000 mg	29Dec2012	14Jan2013		
		24JAN2013	23APR2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombose prophylaxis	40 mg 1x	22Jan2013	27Jan2013		
		24JAN2013	23APR2013	DALACIN	CLINDAMYCIN	ANTIBACTERIALS FOR SYSTEMIC USE	TOOTH ROOT INFLAMMATION	300 mg	07Sep2013	06Oct2013		
		24JAN2013	23APR2013	DALACIN	CLINDAMYCIN	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	TOOTH ROOT INFLAMMATION	300 mg	07Sep2013	06Oct2013		
		24JAN2013	23APR2013	DALACIN	CLINDAMYCIN	ANTI-ACNE PREPARATIONS	TOOTH ROOT INFLAMMATION	300 mg	07Sep2013	06Oct2013		
		24JAN2013	23APR2013	AZITHROMYCIN	AZITHROMYCIN	OPHTHALMOLOGICA LS	Other: SORE THROAT	500 mg	31Mar2014	02Apr2014		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0110	ND basic	24JAN2013	23APR2013	AZITHROMYCIN	AZITHROMYCIN	ANTI-ACNE PREPARATIONS	Other: SORE THROAT	500 mg	31Mar2014	02Apr2014		
		24JAN2013	23APR2013	AZITHROMYCIN	AZITHROMYCIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: SORE THROAT	500 mg	31Mar2014	02Apr2014		
		24JAN2013	23APR2013	DUROTIV - Esomeprazol	ESOMEPRAZOLE	DRUGS FOR ACID RELATED DISORDERS	Other: ANTRUMGASTRITIS	40 mg	28Nov2013	26Dec2013		
		24JAN2013	23APR2013	Novalgine (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Other: Lumbago	500 /if needed	Nov2017		Yes	
		24JAN2013	23APR2013	Zantac	RANITIDINE HYDROCHLORIDE	DRUGS FOR ACID RELATED DISORDERS	Ulcer prophylaxis	300 mg xl	01Jan2010		Yes	
		24JAN2013	23APR2013	Cefuroxin	CEFUROXIME SODIUM	OPHTHALMOLOGICA LS	Prophylaxis for infection surgery	1500 mg 1x	24Jan2013	24Jan2013		
		24JAN2013	23APR2013	Cefuroxin	CEFUROXIME SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Prophylaxis for infection surgery	1500 mg 1x	24Jan2013	24Jan2013		
		24JAN2013	23APR2013	DAFLON	CAPIVEN	VASOPROTECTIVES	2nd DEGREE HAEMHOROIDS	3000 mg	08Nov2013	28Mar2018		
		24JAN2013	23APR2013	CANDIBENE 1%	CLOTRIMAZOLE	ANTIFUNGALS FOR DERMATOLOGICAL USE	Other: PERINEAL ECZEMA	2x/d if needed	19Mar2014	28Mar2018		
		24JAN2013	23APR2013	CANDIBENE 1%	CLOTRIMAZOLE	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: PERINEAL ECZEMA	2x/d if needed	19Mar2014	28Mar2018		
		24JAN2013	23APR2013	CANDIBENE 1%	CLOTRIMAZOLE	OTOLOGICALS	Other: PERINEAL ECZEMA	2x/d if needed	19Mar2014	28Mar2018		
		24JAN2013	23APR2013	CANDIBENE 1%	CLOTRIMAZOLE	OPHTHALMOLOGICA LS	Other: PERINEAL ECZEMA	2x/d if needed	19Mar2014	28Mar2018		
		24JAN2013	23APR2013	CANDIBENE 1%	CLOTRIMAZOLE	ANTIPROTOZOALS	Other: PERINEAL ECZEMA	2x/d if needed	19Mar2014	28Mar2018		
		24JAN2013	23APR2013	CANDIBENE 1%	CLOTRIMAZOLE	STOMATOLOGICAL PREPARATIONS	Other: PERINEAL ECZEMA	2x/d if needed	19Mar2014	28Mar2018		
		24JAN2013	23APR2013	DUROTIV - Esomeprazol	ESOMEPRAZOLE	DRUGS FOR ACID RELATED DISORDERS	Other: ANTRUMGASTRITIS	40 mg	16Jan2014	28Mar2018		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0110	ND basic	24JAN2013	23APR2013	Euthyrox	LEVOTHYROXINE SODIUM	THYROID THERAPY	substantial Hypothyroidism	75 ug x1	Oct2011		Yes	
		24JAN2013	23APR2013	Pantolac	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Ulcers prophylaxe	40 mg 1x	23Apr2013	25Apr2013		
		24JAN2013	23APR2013	SCHERIPROCT SUPP. (prednisolone-cap ronat, cinchocaine-hydro chloride)	SCHERIPROCT /01814801/	VASOPROTECTIVES	2nd DEGREE HAEMHORROIDS	1 daily	08Nov2013	13Nov2013		
		24JAN2013	23APR2013	Simvastadin	SIMVASTATIN	LIPID MODIFYING AGENTS	Other: HYPERCHOLESTERO LEMIA	20 mg	05Apr2017		Yes	
		24JAN2013	23APR2013	Rheumess (Metamizole)	METAMIZOLE	ANALGESICS	Pain	3 ml x1	14Jan2013	17Jan2013		
		24JAN2013	23APR2013	Lendorm	BROTIZOLAM	PSYCHOLEPTICS	sleep inducing (prophylactic)	0.25 mg 1x	22Apr2013	25Apr2013		
		24JAN2013	23APR2013	AETHOXYSKLEROL	POLIDOCANOL	VASOPROTECTIVES	2nd DEGREE HAEMHORROIDS	1.2 ml	07Nov2013	07Nov2013		
		24JAN2013	23APR2013	AETHOXYSKLEROL	POLIDOCANOL	OTHER DERMATOLOGICAL PREPARATIONS	2nd DEGREE HAEMHORROIDS	1.2 ml	07Nov2013	07Nov2013		
		24JAN2013	23APR2013	Voltaren	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	50 mg x1	05Jan2013	12Jan2013		
		24JAN2013	23APR2013	Voltaren	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	50 mg x1	05Jan2013	12Jan2013		
		24JAN2013	23APR2013	Voltaren	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain	50 mg x1	05Jan2013	12Jan2013		
		24JAN2013	23APR2013	Voltaren	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain	50 mg x1	05Jan2013	12Jan2013		
		24JAN2013	23APR2013	Voltaren	DICLOFENAC	OPHTHALMOLOGICA LS	Pain	50 mg x1	05Jan2013	12Jan2013		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0110	ND basic	24JAN2013	23APR2013	Voltaren	DICLOFENAC	THROAT PREPARATIONS	Pain	50 mg x1	05Jan2013	12Jan2013	
		24JAN2013	23APR2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thombose prophylacis	40 mg 1x	22Apr2013	25Apr2013	
		24JAN2013	23APR2013	CAVILON OINTMENT	DIMETICONE	EMOLLIENTS AND PROTECTIVES	PERINEAL ECZEMA	2 x daily	07Nov2013	28Mar2018	
		24JAN2013	23APR2013	CAVILON OINTMENT	DIMETICONE	ANTI-ACNE PREPARATIONS	PERINEAL ECZEMA	2 x daily	07Nov2013	28Mar2018	
		24JAN2013	23APR2013	CAVILON OINTMENT	DIMETICONE	STOMATOLOGICAL PREPARATIONS	PERINEAL ECZEMA	2 x daily	07Nov2013	28Mar2018	
		24JAN2013	23APR2013	CAVILON OINTMENT	DIMETICONE	DRUGS FOR FUNCTIONAL GASTROINTESTINA L DISORDERS	PERINEAL ECZEMA	2 x daily	07Nov2013	28Mar2018	
		24JAN2013	23APR2013	CAVILON OINTMENT	DIMETICONE	ECTOPARASITICID ES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS	PERINEAL ECZEMA	2 x daily	07Nov2013	28Mar2018	
		24JAN2013	23APR2013	CAVILON OINTMENT	DIMETICONE	OPHTHALMOLOGICA LS	PERINEAL ECZEMA	2 x daily	07Nov2013	28Mar2018	
		24JAN2013	23APR2013	Diclobene	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain	75 mg x1	18Jan2013	21Jan2013	
		24JAN2013	23APR2013	Diclobene	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain	75 mg x1	18Jan2013	21Jan2013	
		24JAN2013	23APR2013	Diclobene	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain	75 mg x1	18Jan2013	21Jan2013	
		24JAN2013	23APR2013	Diclobene	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain	75 mg x1	18Jan2013	21Jan2013	
		24JAN2013	23APR2013	Diclobene	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	75 mg x1	18Jan2013	21Jan2013	
		24JAN2013	23APR2013	Diclobene	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	75 mg x1	18Jan2013	21Jan2013	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0110	ND basic	24JAN2013	23APR2013	Locabisol	FUSAFUNGINE	NASAL PREPARATIONS	Asthma	5 ml if needed	2011		Yes	
		24JAN2013	23APR2013	Locabisol	FUSAFUNGINE	THROAT PREPARATIONS	Asthma	5 ml if needed	2011		Yes	
		24JAN2013	23APR2013	Locabisol	FUSAFUNGINE	ANTIBACTERIALS FOR SYSTEMIC USE	Asthma	5 ml if needed	2011		Yes	
		24JAN2013	23APR2013	OAK BARK BATH	QUERCUS SPP. BARK EXTRACT	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	PERINEAL ECZEMA	1 bath if needed	Nov2013	28Mar2018		
		24JAN2013	23APR2013	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Ulcer prophylaxis	40 mg x1	22Jan2013	28Jan2013		
		24JAN2013	23APR2013	BUSCOPAN	HYOSCINE BUTYLBROMIDE	DRUGS FOR FUNCTIONAL GASTROINTESTINA L DISORDERS	DIARRHEA	1000 mg	20Dec2014	22Dec2014		
		24JAN2013	23APR2013	Lendorm	BROTIZOLAM	PSYCHOLEPTICS	sleep inducing (prophylactic)	0.25 mg 1x	23Jan2013	27Jan2013		
01/0111	ND plus	12MAR2013	11JUN2013	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Ulcus prophylaxys	40 mg one/day	13Mar2013	25Mar2013		
		12MAR2013	11JUN2013	PENICILLIN trade name un	PENICILLIN NOS	ALL OTHER NON-THERAPEUTIC PRODUCTS	Other: INFECTION THROAT	2000 mg	15Aug2014	20Aug2014		
		12MAR2013	11JUN2013	PENICILLIN trade name un	PENICILLIN NOS	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION THROAT	2000 mg	15Aug2014	20Aug2014		
		12MAR2013	11JUN2013	Ibuprophen	IBUPROFEN	THROAT PREPARATIONS	Pain - other	500 mg x2	24Apr2017	08May2017		
		12MAR2013	11JUN2013	Ibuprophen	IBUPROFEN	CARDIAC THERAPY	Pain - other	500 mg x2	24Apr2017	08May2017		
		12MAR2013	11JUN2013	Ibuprophen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain - other	500 mg x2	24Apr2017	08May2017		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0111	ND plus	12MAR2013	11JUN2013	Ibuprophen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain - other	500 mg x2	24Apr2017	08May2017	
		12MAR2013	11JUN2013	Ibuprophen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain - other	500 mg x2	24Apr2017	08May2017	
		12MAR2013	11JUN2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombo prophylaxis	40 mg one/d	13Mar2013	14Mar2013	
		12MAR2013	11JUN2013	PENICILLIN trade name un	PENICILLIN NOS	ANTIBACTERIALS FOR SYSTEMIC USE	Other: ERYTHEMA	2000 mg	20Mar2015	25Mar2015	
		12MAR2013	11JUN2013	PENICILLIN trade name un	PENICILLIN NOS	ALL OTHER NON-THERAPEUTIC PRODUCTS	Other: ERYTHEMA	2000 mg	20Mar2015	25Mar2015	
		12MAR2013	11JUN2013	Dicloebene	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain - other	as needed	24Apr2017	08May2017	
		12MAR2013	11JUN2013	Dicloebene	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain - other	as needed	24Apr2017	08May2017	
		12MAR2013	11JUN2013	Dicloebene	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain - other	as needed	24Apr2017	08May2017	
		12MAR2013	11JUN2013	Dicloebene	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain - other	as needed	24Apr2017	08May2017	
		12MAR2013	11JUN2013	Dicloebene	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain - other	as needed	24Apr2017	08May2017	
		12MAR2013	11JUN2013	Dicloebene	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain - other	as needed	24Apr2017	08May2017	
		12MAR2013	11JUN2013	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other Ulcus - Prophylaxis	20 mg x2	24Apr2017	08May2017	
		12MAR2013	11JUN2013	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Prophylaxis infection	1.5 g once	12Mar2013	12Mar2013	
		12MAR2013	11JUN2013	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Prophylaxis infection	1.5 g once	12Mar2013	12Mar2013	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0111	ND plus	12MAR2013	11JUN2013	AUREOCORT	AUREODELF	CORTICOSTEROIDS	Other: ERYTHEMA	2 x daily	22Mar2015	07Apr2015	
		12MAR2013	11JUN2013	Fragmin (Dalteparin-Natrium)	DALTEPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other Prophylaxis for thrombosis	5000 IE	21Jan2018	02Feb2018	
		12MAR2013	11JUN2013	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Ulcer prophylaxis	40 mg one/day	12Jun2013	13Jun2013	
		12MAR2013	11JUN2013	Lendorm	BROTIZOLAM	PSYCHOLEPTICS	for sleeping (prophylactic)	0.25 mg one/day	14Mar2013	14Mar2013	
		12MAR2013	11JUN2013	Lendorm	BROTIZOLAM	PSYCHOLEPTICS	for sleeping (prophylactic)	0.25 mg one/day	11Jun2013	12Jun2013	
01/0112	ND basic	26MAR2013	-	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Ulcer Prophylaxis	20 mg 1x	25Mar2013	29Mar2013	
		26MAR2013	-	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	tromboprophylaxis	40 mg 1x	26Mar2013	28Mar2013	
		26MAR2013	-	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICALS	Prophylaxis	1.5 g 1x	26Mar2013	26Mar2013	
		26MAR2013	-	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Prophylaxis	1.5 g 1x	26Mar2013	26Mar2013	
		26MAR2013	-	Deflamat	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain	100 mg if needed	15Jan2013	25Mar2013	
		26MAR2013	-	Deflamat	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	100 mg if needed	15Jan2013	25Mar2013	
		26MAR2013	-	Deflamat	DICLOFENAC SODIUM	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	Pain	100 mg if needed	15Jan2013	25Mar2013	
		26MAR2013	-	Deflamat	DICLOFENAC SODIUM	OPHTHALMOLOGICALS	Pain	100 mg if needed	15Jan2013	25Mar2013	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0112	ND basic	26MAR2013	-	Deflamat	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain	100 mg if needed	15Jan2013	25Mar2013	
		26MAR2013	-	Deflamat	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain	100 mg if needed	15Jan2013	25Mar2013	
		26MAR2013	-	Pantoloc	PANTOPRAZOLE SODIUM	DRUGS FOR ACID RELATED	Ulcer prophylaxis	20 mg 1x	03Apr2013	07Apr2013	
		26MAR2013	-	Lovenox	SESQUIHYDRATE ENOXAPARIN SODIUM	DISORDERS ANTITHROMBOTIC AGENTS	thrombo prophylaxis	40 mg 1x	04Apr2013	06Apr2013	
01/0113	ND basic	23MAY2013	06AUG2013	Proxen/Naproxen	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	500 mg on demand	09May2013	09Aug2013	
		23MAY2013	06AUG2013	Proxen/Naproxen	NAPROXEN	ANTIINFLAMMATO RY AND ANTIRHEUMATIC PRODUCTS	Pain	500 mg on demand	09May2013	09Aug2013	
		23MAY2013	06AUG2013	Proxen/Naproxen	NAPROXEN	OTHER GYNECOLOGICALS	Pain	500 mg on demand	09May2013	09Aug2013	
		23MAY2013	06AUG2013	Proxen/Naproxen	NAPROXEN	OPHTHALMOLOGICA LS	Pain	500 mg on demand	09May2013	09Aug2013	
		23MAY2013	06AUG2013	Proxen/Naproxen	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Pain	500 mg on demand	09May2013	09Aug2013	
		23MAY2013	06AUG2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombosis prophylaxis	40 mg	05Aug2013	09Aug2013	
		23MAY2013	06AUG2013	CLINDAMYCIN	CLINDAMYCIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: SPONDYLODISCITI S	900 mg	25Sep2014	02Oct2014	
		23MAY2013	06AUG2013	CLINDAMYCIN	CLINDAMYCIN	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: SPONDYLODISCITI S	900 mg	25Sep2014	02Oct2014	
		23MAY2013	06AUG2013	CLINDAMYCIN	CLINDAMYCIN	ANTI-ACNE PREPARATIONS	Other: SPONDYLODISCITI S	900 mg	25Sep2014	02Oct2014	
		23MAY2013	06AUG2013	RIFOLDIN	RIFAMPICIN	ANTIMYCOBACTERI ALS	Other: SPONDYLODISCITI S	900 mg	15Oct2014	21Nov2014	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0113	ND basic	23MAY2013	06AUG2013	RIFOLDIN	RIFAMPICIN	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: SPONDYLODISCITI S	900 mg	15Oct2014	21Nov2014		
		23MAY2013	06AUG2013	RIFOLDIN	RIFAMPICIN	OPHTHALMOLOGICA LS	Other: SPONDYLODISCITI S	900 mg	15Oct2014	21Nov2014		
		23MAY2013	06AUG2013	TRAMAL	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain - other	100 mg	02Oct2014	01Nov2014		
		23MAY2013	06AUG2013	Parkemed	MEFENAMIC ACID	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	500 mg on demand	09May2013	09Aug2013		
		23MAY2013	06AUG2013	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	infection prophylaxis	1.5 g	23May2013	23May2013		
		23MAY2013	06AUG2013	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	infection prophylaxis	1.5 g	23May2013	23May2013		
		23MAY2013	06AUG2013	VANCOMYCIN	VANCOMYCIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: SPONDYLODISCITI S	2000 mg	02Oct2014	04Oct2014		
		23MAY2013	06AUG2013	VANCOMYCIN	VANCOMYCIN	OPHTHALMOLOGICA LS	Other: SPONDYLODISCITI S	2000 mg	02Oct2014	04Oct2014		
		23MAY2013	06AUG2013	VANCOMYCIN	VANCOMYCIN	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: SPONDYLODISCITI S	2000 mg	02Oct2014	04Oct2014		
		23MAY2013	06AUG2013	OSPEXIN	CEFALEXIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: SPONDYLODISCITI S	3000 mg	15Oct2014	02Jan2015		
		23MAY2013	06AUG2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombosisproph ylaxis	40 mg	22May2013	26May2013		
		23MAY2013	06AUG2013	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: SPONDYLODISCITI S	4500 mg	02Oct2014	15Oct2014		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0113	ND basic	23MAY2013	06AUG2013	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: SPONDYLODISCITI S	4500 mg	02Oct2014	15Oct2014		
		23MAY2013	06AUG2013	PANTOLAC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	02Oct2014	01Nov2014		
		23MAY2013	06AUG2013	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Ulcers prophylaxis	40 mg	22May2013	27May2013		
		23MAY2013	06AUG2013	FOSFOMYCIN	FOSFOMYCIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: SPONDYLODISCITI S	8000 mg	04Oct2014	15Oct2014		
		23MAY2013	06AUG2013	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain - other	1200 mg	02Oct2014	01Nov2014		
		23MAY2013	06AUG2013	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain - other	1200 mg	02Oct2014	01Nov2014		
		23MAY2013	06AUG2013	Lendorm	BROTIZOLAM	PSYCHOLEPTICS	sleep indication (prophylactic)	0.25 mg	22May2013	26May2013		
		23MAY2013	06AUG2013	Enterobene	LOPERAMIDE HYDROCHLORIDE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Diarrhea	8 mg	26May2013	26May2013		
		23MAY2013	06AUG2013	Antibiophilus	LACTOBACILLUS ACIDOPHILUS	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Diarrhea	4.5 g	26May2013	27May2013		
		23MAY2013	06AUG2013	Antibiophilus	LACTOBACILLUS ACIDOPHILUS	OTHER GYNECOLOGICALS	Diarrhea	4.5 g	26May2013	27May2013		
		23MAY2013	06AUG2013	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Ulcers prophylaxis	40 g	05Aug2013	09Aug2013		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0114	ND basic	11JUN2013	11SEP2013	Euthyrox	LEVOTHYROXINE SODIUM	THYROID THERAPY	Hypothyroidism	100 ug Sa + So	Apr2000		Yes	
		11JUN2013	11SEP2013	CLAVAMOX	SPEKTRAMOX	ANTIBACTERIALS FOR SYSTEMIC USE	Other: COMMON COLD	2000 mg	07Feb2015	12Feb2015		
		11JUN2013	11SEP2013	GENTAX gtt (Gentamicin)	GENTAMICIN SULFATE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: conjunctivitis	3/day	Jul2016	Jul2016		
		11JUN2013	11SEP2013	GENTAX gtt (Gentamicin)	GENTAMICIN SULFATE	OTOLOGICALS	Other: conjunctivitis	3/day	Jul2016	Jul2016		
		11JUN2013	11SEP2013	GENTAX gtt (Gentamicin)	GENTAMICIN SULFATE	OPHTHALMOLOGICA LS	Other: conjunctivitis	3/day	Jul2016	Jul2016		
		11JUN2013	11SEP2013	GENTAX gtt (Gentamicin)	GENTAMICIN SULFATE	ANTIBACTERIALS FOR SYSTEMIC USE	Other: conjunctivitis	3/day	Jul2016	Jul2016		
		11JUN2013	11SEP2013	GENTAX gtt (Gentamicin)	GENTAMICIN SULFATE	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: conjunctivitis	3/day	Jul2016	Jul2016		
		11JUN2013	11SEP2013	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain - other	2 x 200 mg	14Dec2017	31Dec2017		
		11JUN2013	11SEP2013	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain - other	2 x 200 mg	14Dec2017	31Dec2017		
		11JUN2013	11SEP2013	Euthyrox	LEVOTHYROXINE SODIUM	THYROID THERAPY	Hypothyroidism	125 ug Mo-Fr	Apr2000		Yes	
		11JUN2013	11SEP2013	PASPERTIN (Metoclopramid, Hydrochlorid, Monohydrat)	METOCLOPRAMIDE HYDROCHLORIDE	DRUGS FOR FUNCTIONAL GASTROINTESTINA L DISORDERS	Other: NAUSEA (MIGRAINE)	10 mg	Mar2014		Yes	
		11JUN2013	11SEP2013	Paracetamol	PARACETAMOL	ANALGESICS	Pain - other	4 x 450 mg	14Dec2017	31Dec2017		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0114	ND basic	11JUN2013	11SEP2013	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	ulcus prophylaxis	40 mg	Nov2012		Yes	
		11JUN2013	11SEP2013	Orphenadrin	ORPHENADRINE HYDROCHLORIDE	ANTI-PARKINSON DRUGS	Pain - other	4 x 35 mg	14Dec2017	31Dec2017		
		11JUN2013	11SEP2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombosisprophylaxis	40 mg	09Jun2013	14Jun2013		
		11JUN2013	11SEP2013	Paracetamol	PARACETAMOL	ANALGESICS	Other - influenza	2 x 500 mg	Mar2018	Mar2018		
		11JUN2013	11SEP2013	Lendorm	BROTIZOLAM	PSYCHOLEPTICS	for sleeping (prophylactic)	0.25 mg	11Jun2013	13Jun2013		
		11JUN2013	11SEP2013	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICALS	Prophylaxe infection	1.5 mg	11Jun2013	11Jun2013		
		11JUN2013	11SEP2013	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Prophylaxe infection	1.5 mg	11Jun2013	11Jun2013		
01/0115	ND plus	12JUN2013	17SEP2013	Voltaren ret	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain	150 mg	29May2013	10Jun2013		
		12JUN2013	17SEP2013	Voltaren ret	DICLOFENAC	THROAT PREPARATIONS	Pain	150 mg	29May2013	10Jun2013		
		12JUN2013	17SEP2013	Voltaren ret	DICLOFENAC	OPHTHALMOLOGICALS	Pain	150 mg	29May2013	10Jun2013		
		12JUN2013	17SEP2013	Voltaren ret	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	150 mg	29May2013	10Jun2013		
		12JUN2013	17SEP2013	Voltaren ret	DICLOFENAC	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	Pain	150 mg	29May2013	10Jun2013		
		12JUN2013	17SEP2013	Voltaren ret	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain	150 mg	29May2013	10Jun2013		
		12JUN2013	17SEP2013	CLINDAMYCIN ALTRERNOVA	CLINDAMYCIN HYDROCHLORIDE	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	ENDODONTIC TREATMENT	300 mg	24Oct2013	02Nov2013		
		12JUN2013	17SEP2013	CLINDAMYCIN ALTRERNOVA	CLINDAMYCIN HYDROCHLORIDE	ANTI-ACNE PREPARATIONS	ENDODONTIC TREATMENT	300 mg	24Oct2013	02Nov2013		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0115	ND plus	12JUN2013	17SEP2013	CLINDAMYCIN ALTERNOVA	CLINDAMYCIN HYDROCHLORIDE	ANTIBACTERIALS FOR SYSTEMIC USE	ENDODONTIC TREATMENT	300 mg	24Oct2013	02Nov2013		
		12JUN2013	17SEP2013	VALSACOR	VALSARTAN	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Other: HYPERTONIA	160 mg	11Mar2014		Yes	
		12JUN2013	17SEP2013	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Ulcers prophylaxis	40 mg	11Jun2013	15Jun2013		
		12JUN2013	17SEP2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombosis prophylaxis	40 mg	10Jun2013	15Jun2013		
		12JUN2013	17SEP2013	Lendorm	BROTIZOLAM	PSYCHOLEPTICS	sleep inducing (prophylactic)	0.25 mg	10Jun2013	14Jun2013		
		12JUN2013	17SEP2013	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	ulcers prophylaxis	40 mg	17Sep2013	17Sep2013		
		12JUN2013	17SEP2013	Lendorm	BROTIZOLAM	PSYCHOLEPTICS	sleep inducing (prophylactic)	0.25 mg	16Sep2013	18Sep2013		
01/0116	ND basic	18JUN2013	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1200 mg (600 mg 2 X) on demand	12Jun2013		Yes	
		18JUN2013	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1200 mg (600 mg 2 X) on demand	12Jun2013		Yes	
		18JUN2013	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain	1200 mg (600 mg 2 X) on demand	12Jun2013		Yes	
		18JUN2013	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain	1200 mg (600 mg 2 X) on demand	12Jun2013		Yes	
		18JUN2013	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain	1200 mg (600 mg 2 X) on demand	12Jun2013		Yes	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0116	ND basic	18JUN2013	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	ulcus prophylaxis	40 mg 1 X	17Jun2013	20Jun2013		
		18JUN2013	-	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombosis prophylaxis	40 mg 1 X	17Jun2013	20Jun2013		
		18JUN2013	-	Cefuroxin	CEFUROXIME SODIUM	OPHTHALMOLOGICA LS	infection prophylaxis	1.5 mg 1 X	18Jun2013	18Jun2013		
		18JUN2013	-	Cefuroxin	CEFUROXIME SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	infection prophylaxis	1.5 mg 1 X	18Jun2013	18Jun2013		
01/0118	ND plus	10JUL2013	08OCT2013	Hydal	HYDROMORPHONE HYDROCHLORIDE	ANALGESICS	Pain	12 mg if needed	10Apr2013		Yes	
		10JUL2013	08OCT2013	Praxiten	OXAZEPAM	PSYCHOLEPTICS	insomnia	15 mg if needed	02Mar2014		Yes	
		10JUL2013	08OCT2013	Neurontin	GABAPENTIN	ANALGESICS	Other neuropathic pain	6 x 300 mg	16Jan2018		Yes	
		10JUL2013	08OCT2013	Neurontin	GABAPENTIN	OTHER NERVOUS SYSTEM DRUGS	Other neuropathic pain	6 x 300 mg	16Jan2018		Yes	
		10JUL2013	08OCT2013	Neurontin	GABAPENTIN	ANTIEPILEPTICS	Other neuropathic pain	6 x 300 mg	16Jan2018		Yes	
		10JUL2013	08OCT2013	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	ulcera prophylaxis	20 mg if needed	10Apr2013		Yes	
		10JUL2013	08OCT2013	Neurontin	GABAPENTIN	OTHER NERVOUS SYSTEM DRUGS	neuropathic pain	600 mg	09Jul2014		Yes	
		10JUL2013	08OCT2013	Neurontin	GABAPENTIN	ANTIEPILEPTICS	neuropathic pain	600 mg	09Jul2014		Yes	
		10JUL2013	08OCT2013	Neurontin	GABAPENTIN	ANALGESICS	neuropathic pain	600 mg	09Jul2014		Yes	
		10JUL2013	08OCT2013	Seractil forte	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain - other	3 x 400 mg	01Feb2018		Yes	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0118	ND plus	10JUL2013	08OCT2013	Seractil forte	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain - other	3 x 400 mg	01Feb2018		Yes	
		10JUL2013	08OCT2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombose prophylaxis	20 mg	08Jul2013	15Jul2013		
		10JUL2013	08OCT2013	Metagelan	METAMIZOLE	ANALGESICS	Pain - other	3 x 500 mg	16Jan2018		Yes	
		10JUL2013	08OCT2013	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	infection prophylaxis	1.5 mg	10Jul2013	10Jul2013		
		10JUL2013	08OCT2013	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	infection prophylaxis	1.5 mg	10Jul2013	10Jul2013		
		10JUL2013	08OCT2013	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombose prophylaxis	20 mg	07Oct2013	11Oct2013		
01/0119	ND basic	10JUL2013	08OCT2013	Influbene	INFLUBENE	ANALGESICS	common cold	1 bag	19Nov2013	23Nov2013		
		/01141901/										
		23JUL2013	15OCT2013	SIMVASTATIN	SIMVASTATIN	LIPID MODIFYING AGENTS	HYPERCHOLESTERO LANAEMIA	10 MG	May2013		Yes	
		23JUL2013	15OCT2013	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	ULCERA PROPHYLAXIS	40 MG	16Oct2013	18Oct2013		
		23JUL2013	15OCT2013	Thrombo ASS	ACETYLSALICYLIC ACID	STOMATOLOGICAL PREPARATIONS	Other: hypercholesteri naemia	100 mg	Oct2014		Yes	
		23JUL2013	15OCT2013	Thrombo ASS	ACETYLSALICYLIC ACID	ANTITHROMBOTIC AGENTS	Other: hypercholesteri naemia	100 mg	Oct2014		Yes	
01/0119	ND basic	23JUL2013	15OCT2013	Thrombo ASS	ACETYLSALICYLIC ACID	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: hypercholesteri naemia	100 mg	Oct2014		Yes	
		23JUL2013	15OCT2013	Thrombo ASS	ACETYLSALICYLIC ACID	ANALGESICS	Other: hypercholesteri naemia	100 mg	Oct2014		Yes	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0119	ND basic	23JUL2013	15OCT2013	DICLOBENE	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Other: LUMBAGO	150 mg	14Jul2014	27Jul2014		
		23JUL2013	15OCT2013	DICLOBENE	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: LUMBAGO	150 mg	14Jul2014	27Jul2014		
		23JUL2013	15OCT2013	DICLOBENE	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: LUMBAGO	150 mg	14Jul2014	27Jul2014		
		23JUL2013	15OCT2013	DICLOBENE	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Other: LUMBAGO	150 mg	14Jul2014	27Jul2014		
		23JUL2013	15OCT2013	DICLOBENE	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Other: LUMBAGO	150 mg	14Jul2014	27Jul2014		
		23JUL2013	15OCT2013	DICLOBENE	DICLOFENAC SODIUM	THROAT PREPARATIONS	Other: LUMBAGO	150 mg	14Jul2014	27Jul2014		
		23JUL2013	15OCT2013	Neodolpasse infusion	NEODOLPASSE	MUSCLE RELAXANTS	Pain - other	UNK	Aug2017	Aug2017		
		23JUL2013	15OCT2013	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other Ulcus prophylaxis	UNK	11Oct2017	Nov2018		
		23JUL2013	15OCT2013	MEXALEN	PARACETAMOL	ANALGESICS	PAIN	1000 MG	19Jul2013	20Jul2013		
		23JUL2013	15OCT2013	Atorvastatin	ATORVASTATIN	LIPID MODIFYING AGENTS	Other: hypercholesterolaemia	80 mg	Oct2014		Yes	
		23JUL2013	15OCT2013	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	14Jul2014	27Jul2014		
		23JUL2013	15OCT2013	Seractil forte	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain - other	400 mg	Aug2017	Nov2018		
		23JUL2013	15OCT2013	Seractil forte	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain - other	400 mg	Aug2017	Nov2018		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0119	ND basic	23JUL2013	15OCT2013	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain - other	300 mg if needed	10Oct2018		Yes	
		23JUL2013	15OCT2013	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain - other	300 mg if needed	10Oct2018		Yes	
		23JUL2013	15OCT2013	PROXEN (NAPROXEN)	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	PAIN	1000 MG	19Jul2013	20Jul2013		
		23JUL2013	15OCT2013	PROXEN (NAPROXEN)	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	PAIN	1000 MG	19Jul2013	20Jul2013		
		23JUL2013	15OCT2013	PROXEN (NAPROXEN)	NAPROXEN	OTHER GYNECOLOGICALS	PAIN	1000 MG	19Jul2013	20Jul2013		
		23JUL2013	15OCT2013	PROXEN (NAPROXEN)	NAPROXEN	STOMATOLOGICAL PREPARATIONS	PAIN	1000 MG	19Jul2013	20Jul2013		
		23JUL2013	15OCT2013	PROXEN (NAPROXEN)	NAPROXEN	OPHTHALMOLOGICA LS	PAIN	1000 MG	19Jul2013	20Jul2013		
		23JUL2013	15OCT2013	Sirdalud 4 mg	TIZANIDINE HYDROCHLORIDE	MUSCLE RELAXANTS	musclspasticit y treatment	4 mg 0-0-0-1	25Sep2017	Nov2018		
		23JUL2013	15OCT2013	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	THROMBOSIS PROPHYLAXIS	40 MG	22Jul2013	26Jul2013		
		23JUL2013	15OCT2013	Diclobene 75 mg	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain - other	UNK	11Oct2017	Nov2018		
		23JUL2013	15OCT2013	Diclobene 75 mg	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain - other	UNK	11Oct2017	Nov2018		
		23JUL2013	15OCT2013	Diclobene 75 mg	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain - other	UNK	11Oct2017	Nov2018		
		23JUL2013	15OCT2013	Diclobene 75 mg	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain - other	UNK	11Oct2017	Nov2018		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0119	ND basic	23JUL2013	15OCT2013	Diclobene 75 mg	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain - other	UNK	11Oct2017	Nov2018	
		23JUL2013	15OCT2013	Diclobene 75 mg	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain - other	UNK	11Oct2017	Nov2018	
		23JUL2013	15OCT2013	LENDORM	BROTIZOLAM	PSYCHOLEPTICS	SLEEPING INDUCTION PROPHYLAXIS	0.25 MG	21Jul2013	25Jul2013	
		23JUL2013	15OCT2013	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	ULCERA PROPHYLAXIS	40 MG	22Jul2013	27Jul2013	
		23JUL2013	15OCT2013	CEFEROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	INFECTION PROPHYLAXIS	1500 MG	23Jul2013	23Jul2013	
		23JUL2013	15OCT2013	CEFEROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	INFECTION PROPHYLAXIS	1500 MG	23Jul2013	23Jul2013	
		23JUL2013	15OCT2013	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	THROMBOSIS PROPHYLAXIS	40 MG	14Oct2013	18Oct2013	
01/0121	ND plus	15OCT2013	14JAN2014	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	ulcera prophylaxis	40 mg	16Oct2013	19Oct2013	
		15OCT2013	14JAN2014	BIOCEF (Cefpodoxim-Proex il)	CEFPODOXIME PROXETIL	ANTIBACTERIALS FOR SYSTEMIC USE	Other: COMMON COLD	400 mg	01Nov2015	08Nov2015	
		15OCT2013	14JAN2014	Lendorm	BROTIZOLAM	PSYCHOLEPTICS	insomnia prophylaxis	0.25 mg if needed	16Oct2013	18Oct2013	
		15OCT2013	14JAN2014	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	thrombosis prophylaxis	40 mg	16Oct2013	19Oct2013	
		15OCT2013	14JAN2014	Ceferoxim	CEFUROXIME	OPHTHALMOLOGICA LS	inflammation prophylaxis	1.5 g	15Oct2013	15Oct2013	
		15OCT2013	14JAN2014	Ceferoxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	inflammation prophylaxis	1.5 g	15Oct2013	15Oct2013	
		15OCT2013	14JAN2014	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Ulcers prophylaxis	40 mg	15Jan2014	16Jan2014	
		15OCT2013	14JAN2014	Lendorm	BROTIZOLAM	PSYCHOLEPTICS	insomnia prophylaxis	0.25 mg	14Jan2014	16Jan2014	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0121	ND plus	15OCT2013	14JAN2014	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	thrombosis prophylaxis	40 mg	15Jan2014	16Jan2014	
		15OCT2013	14JAN2014	Neocitran (Ascorbic acid, Paracetamol, Pheniramin-Maleat , Phenylephrin-Hydr ochlorid, Saccharose)	NEO CITRAN /00438101/	ANALGESICS	common cold	1 Sachet	30Jan2014	30Jan2014	
01/0122	ND plus	26SEP2013	17DEC2013	NaCL + Vit. B	VITAMIN B NOS	VITAMINS	Pain	250 ml + 2 ml	18Aug2013	24Sep2013	
		26SEP2013	17DEC2013	NaCL + Vit. B	VITAMIN B NOS	ANTIANEMIC PREPARATIONS	Pain	250 ml + 2 ml	18Aug2013	24Sep2013	
		26SEP2013	17DEC2013	Clovomax	SPEKTRAMOX	ANTIBACTERIALS FOR SYSTEMIC USE	bronchial inflammation	2000 mg	03Mar2014	09Mar2014	
		26SEP2013	17DEC2013	Clavanox 1 g	SPEKTRAMOX	ANTIBACTERIALS FOR SYSTEMIC USE	Other Bronchitis	1 g	30Mar2017	04Apr2017	
		26SEP2013	17DEC2013	Otriven Duo	XYLOMETAZOLINE HYDROCHLORIDE	NASAL PREPARATIONS	Other Sinusitis	3x1 gtt	06Apr2017	12Apr2017	
		26SEP2013	17DEC2013	Otriven Duo	XYLOMETAZOLINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Other Sinusitis	3x1 gtt	06Apr2017	12Apr2017	
		26SEP2013	17DEC2013	Vimovo 500 mg/20 mg (Naproxen, Esomeprazol)	VIMOVO	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain - other	2 x 500 mg/20 mg	06Apr2018	12Apr2018	
		26SEP2013	17DEC2013	DICLOBENE RET	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain	100 mg if needed	18Aug2013	24Sep2013	
		26SEP2013	17DEC2013	DICLOBENE RET	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain	100 mg if needed	18Aug2013	24Sep2013	
		26SEP2013	17DEC2013	DICLOBENE RET	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain	100 mg if needed	18Aug2013	24Sep2013	
		26SEP2013	17DEC2013	DICLOBENE RET	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	100 mg if needed	18Aug2013	24Sep2013	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0122	ND plus	26SEP2013	17DEC2013	DICLOBENE RET	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	100 mg if needed	18Aug2013	24Sep2013	
		26SEP2013	17DEC2013	DICLOBENE RET	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain	100 mg if needed	18Aug2013	24Sep2013	
		26SEP2013	17DEC2013	Acetylcystein Hexal	ACETYLCYSTEINE	COUGH AND COLD PREPARATIONS	expectorant	600 mg	03Mar2014	09Mar2014	
		26SEP2013	17DEC2013	Acetylcystein Hexal	ACETYLCYSTEINE	OPHTHALMOLOGICA LS	expectorant	600 mg	03Mar2014	09Mar2014	
		26SEP2013	17DEC2013	Acetylcystein Hexal	ACETYLCYSTEINE	NASAL PREPARATIONS	expectorant	600 mg	03Mar2014	09Mar2014	
		26SEP2013	17DEC2013	Acetylcystein Hexal	ACETYLCYSTEINE	OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	expectorant	600 mg	03Mar2014	09Mar2014	
		26SEP2013	17DEC2013	Acetylcystein Hexal	ACETYLCYSTEINE	ALL OTHER THERAPEUTIC PRODUCTS	expectorant	600 mg	03Mar2014	09Mar2014	
		26SEP2013	17DEC2013	Mucobene (Acetylcystein)	ACETYLCYSTEINE	NASAL PREPARATIONS	Other Bronchitis	600 mg	30Mar2017	04Apr2017	
		26SEP2013	17DEC2013	Mucobene (Acetylcystein)	ACETYLCYSTEINE	OPHTHALMOLOGICA LS	Other Bronchitis	600 mg	30Mar2017	04Apr2017	
		26SEP2013	17DEC2013	Mucobene (Acetylcystein)	ACETYLCYSTEINE	COUGH AND COLD PREPARATIONS	Other Bronchitis	600 mg	30Mar2017	04Apr2017	
		26SEP2013	17DEC2013	Mucobene (Acetylcystein)	ACETYLCYSTEINE	OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	Other Bronchitis	600 mg	30Mar2017	04Apr2017	
		26SEP2013	17DEC2013	Mucobene (Acetylcystein)	ACETYLCYSTEINE	ALL OTHER THERAPEUTIC PRODUCTS	Other Bronchitis	600 mg	30Mar2017	04Apr2017	
		26SEP2013	17DEC2013	Bionorica Sinupret intens	SINUPRET /00578801/	COUGH AND COLD PREPARATIONS	Other Sinusitis	UNK	06Apr2017	12Apr2017	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0122	ND plus	26SEP2013	17DEC2013	Proxen 500 mg	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain - other	1 x 500 mg	13Apr2018	14Apr2018	
		26SEP2013	17DEC2013	Proxen 500 mg	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain - other	1 x 500 mg	13Apr2018	14Apr2018	
		26SEP2013	17DEC2013	Proxen 500 mg	NAPROXEN	OTHER GYNECOLOGICALS	Pain - other	1 x 500 mg	13Apr2018	14Apr2018	
		26SEP2013	17DEC2013	Proxen 500 mg	NAPROXEN	OPHTHALMOLOGICA LS	Pain - other	1 x 500 mg	13Apr2018	14Apr2018	
		26SEP2013	17DEC2013	Proxen 500 mg	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Pain - other	1 x 500 mg	13Apr2018	14Apr2018	
		26SEP2013	17DEC2013	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	ULCERA PROPHYLAXIS	40 mg	25Sep2013	25Oct2013	
		26SEP2013	17DEC2013	TAVANIC	LEVOFLOXACIN	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	BACTERIAL INFLAMMATION	500 mg	03Nov2014	09Nov2014	
		26SEP2013	17DEC2013	TAVANIC	LEVOFLOXACIN	OPHTHALMOLOGICA LS	BACTERIAL INFLAMMATION	500 mg	03Nov2014	09Nov2014	
		26SEP2013	17DEC2013	TAVANIC	LEVOFLOXACIN	OTOLOGICALS	BACTERIAL INFLAMMATION	500 mg	03Nov2014	09Nov2014	
		26SEP2013	17DEC2013	TAVANIC	LEVOFLOXACIN	ANTIBACTERIALS FOR SYSTEMIC USE	BACTERIAL INFLAMMATION	500 mg	03Nov2014	09Nov2014	
		26SEP2013	17DEC2013	Rhinion 10 ml (Naphazoline hydrochloride)	NAPHAZOLINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Other Bronchitis	2x2 gtt	30Mar2017	04Apr2017	
		26SEP2013	17DEC2013	Rhinion 10 ml (Naphazoline hydrochloride)	NAPHAZOLINE HYDROCHLORIDE	NASAL PREPARATIONS	Other Bronchitis	2x2 gtt	30Mar2017	04Apr2017	
		26SEP2013	17DEC2013	Dramenex (Dimenhydrinat)	DIMENHYDRINATE	ANTI HISTAMINES FOR SYSTEMIC USE	Other Sea Sickness	50 mg	27Aug2017	27Aug2017	
		26SEP2013	17DEC2013	Dramenex (Dimenhydrinat)	DIMENHYDRINATE	OTHER NERVOUS SYSTEM DRUGS	Other Sea Sickness	50 mg	27Aug2017	27Aug2017	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0122	ND plus	26SEP2013	17DEC2013	Dramenex (Dimenhydrinat)	DIMENHYDRINATE	ANTIEMETICS AND ANTINAUSEANTS	Other Sea Sickness	50 mg	27Aug2017	27Aug2017	
		26SEP2013	17DEC2013	Clavamox 875 mg/125 mg (Amoxicillin, clavulanic acid)	SPEKTRAMOX	ANTIBACTERIALS FOR SYSTEMIC USE	Other bronchitis	2 x 875 mg/125 mg	16Nov2018	20Nov2018	
		26SEP2013	17DEC2013	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombosis Prophylaxis	40 mg	25Sep2013	01Oct2013	
		26SEP2013	17DEC2013	OTRIVIN	XYLOMETAZOLINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	SINUSITIS	1-2 puffs	03Nov2014	09Nov2014	
		26SEP2013	17DEC2013	OTRIVIN	XYLOMETAZOLINE HYDROCHLORIDE	NASAL PREPARATIONS	SINUSITIS	1-2 puffs	03Nov2014	09Nov2014	
		26SEP2013	17DEC2013	Josalid 500 mg (Josamycin)	JOSAMYCIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other Sinusitis	500 mg	06Apr2017	12Apr2017	
		26SEP2013	17DEC2013	Dramenex (Dimenhydrinat)	DIMENHYDRINATE	ANTIEMETICS AND ANTINAUSEANTS	Other Sea Sickness	50 mg	03Sep2017	04Sep2017	
		26SEP2013	17DEC2013	Dramenex (Dimenhydrinat)	DIMENHYDRINATE	OTHER NERVOUS SYSTEM DRUGS	Other Sea Sickness	50 mg	03Sep2017	04Sep2017	
		26SEP2013	17DEC2013	Dramenex (Dimenhydrinat)	DIMENHYDRINATE	ANTI HISTAMINES FOR SYSTEMIC USE	Other Sea Sickness	50 mg	03Sep2017	04Sep2017	
		26SEP2013	17DEC2013	Otrivin Duo nasal spray (Ipratropium, Xylometazolin)	XYLOMETAZOLINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Other	2x0.6 mg/ml + 0.5 mg/ml	16Nov2018	20Nov2018	
		26SEP2013	17DEC2013	Otrivin Duo nasal spray (Ipratropium, Xylometazolin)	XYLOMETAZOLINE HYDROCHLORIDE	NASAL PREPARATIONS	Other	2x0.6 mg/ml + 0.5 mg/ml	16Nov2018	20Nov2018	
		26SEP2013	17DEC2013	DORMICUM	MIDAZOLAM	PSYCHOLEPTICS	SLEEPING INDUCTION PROPHYLAXIS	7.5 mg	26Sep2013	26Sep2013	
		26SEP2013	17DEC2013	DRAMENEX	DIMENHYDRINATE	OTHER NERVOUS SYSTEM DRUGS	SEA SICKNESS	50 mg	02Oct2014	12Oct2014	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0122	ND plus	26SEP2013	17DEC2013	DRAMENEX	DIMENHYDRINATE	ANTI HISTAMINES FOR SYSTEMIC USE	SEA SICKNESS	50 mg	02Oct2014	12Oct2014		
		26SEP2013	17DEC2013	DRAMENEX	DIMENHYDRINATE	ANTIEMETICS AND ANTINAUSEANTS	SEA SICKNESS	50 mg	02Oct2014	12Oct2014		
		26SEP2013	17DEC2013	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	ULCERA PROPHYLAXIS	40 mg	18Dec2013	19Dec2013		
		26SEP2013	17DEC2013	NOVALGIN (METAMIZOLE)	METAMIZOLE SODIUM	ANALGESICS	OVER-STRESSED JOINTS RIGHT FOOT	100 mg	26Aug2015	07Sep2015		
		26SEP2013	17DEC2013	CEFUROXIN	CEFUROXIME SODIUM	OPHTHALMOLOGICA LS	INFLAMMATION PROPHYLAXIS	1500 mg	26Sep2013	26Sep2013		
		26SEP2013	17DEC2013	CEFUROXIN	CEFUROXIME SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	INFLAMMATION PROPHYLAXIS	1500 mg	26Sep2013	26Sep2013		
		26SEP2013	17DEC2013	IBUMETIN	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	OVER-STRESSED JOINTS RIGHT FOOT	1500 mg	26Aug2015	07Sep2015		
		26SEP2013	17DEC2013	IBUMETIN	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	OVER-STRESSED JOINTS RIGHT FOOT	1500 mg	26Aug2015	07Sep2015		
		26SEP2013	17DEC2013	IBUMETIN	IBUPROFEN	OTHER GYNECOLOGICALS	OVER-STRESSED JOINTS RIGHT FOOT	1500 mg	26Aug2015	07Sep2015		
		26SEP2013	17DEC2013	IBUMETIN	IBUPROFEN	CARDIAC THERAPY	OVER-STRESSED JOINTS RIGHT FOOT	1500 mg	26Aug2015	07Sep2015		
		26SEP2013	17DEC2013	IBUMETIN	IBUPROFEN	THROAT PREPARATIONS	OVER-STRESSED JOINTS RIGHT FOOT	1500 mg	26Aug2015	07Sep2015		
		26SEP2013	17DEC2013	LEXOTANIL	BROMAZEPAM	PSYCHOLEPTICS	INSOMNIA (PAIN!)	3 mg	11Jun2016	15Jun2016		
01/0123	ND plus	16SEP2014	19DEC2014	SERTRALIN	SERTRALINE	PSYCHOANALEPTIC S	Other: ANXIETY (MedHis no. 01)	50 mg	07Jan2014		Yes	MH-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0123	ND plus	16SEP2014	19DEC2014	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	16Sep2014	16Sep2014		
		16SEP2014	19DEC2014	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	16Sep2014	16Sep2014		
		16SEP2014	19DEC2014	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	19Dec2014	20Dec2014		
		16SEP2014	19DEC2014	PARACODIN	DIHYDROCODEINE	ANALGESICS	Other: COMMON COLD (AE no. 01)	30 mg	18Feb2015	02Mar2015		AE-1
		16SEP2014	19DEC2014	Diclobene	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 04)	200 mg if needed	Nov2016		Yes	AE-4
		16SEP2014	19DEC2014	Diclobene	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 04)	200 mg if needed	Nov2016		Yes	AE-4
		16SEP2014	19DEC2014	Diclobene	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 04)	200 mg if needed	Nov2016		Yes	AE-4
		16SEP2014	19DEC2014	Diclobene	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain-other (AE no. 04)	200 mg if needed	Nov2016		Yes	AE-4
		16SEP2014	19DEC2014	Diclobene	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain-other (AE no. 04)	200 mg if needed	Nov2016		Yes	AE-4
		16SEP2014	19DEC2014	Diclobene	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 04)	200 mg if needed	Nov2016		Yes	AE-4
		16SEP2014	19DEC2014	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 05)	400 mg a 1-1-1/1200 mg	06Mar2017	Jul2019		AE-5
		16SEP2014	19DEC2014	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 05)	400 mg a 1-1-1/1200 mg	06Mar2017	Jul2019		AE-5

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0123	ND plus	16SEP2014	19DEC2014	Escitalopram	ESCITALOPRAM	PSYCHOANALEPTICS	Other: Depression (MedHis no. 01)	10 mg 1-0-0	2018		Yes	MH-1
		16SEP2014	19DEC2014	PRONERV	NEUROBION	VITAMINS	Other: NERVE REGENERATION	1 capsule	01Oct2014	Dec2015		
		16SEP2014	19DEC2014	PRONERV	/00176001/ NEUROBION	ANTIEMETICS AND ANTINAUSEANTS	Other: NERVE REGENERATION	1 capsule	01Oct2014	Dec2015		
		16SEP2014	19DEC2014	NEURONTIN	/00176001/ GABAPENTIN	ANALGESICS	Other: NEUROPATHIC PAIN (AE no. 03)	1800 mg	02Jul2015	17Dec2015		AE-3
		16SEP2014	19DEC2014	NEURONTIN	GABAPENTIN	ANTIEPILEPTICS	Other: NEUROPATHIC PAIN (AE no. 03)	1800 mg	02Jul2015	17Dec2015		AE-3
		16SEP2014	19DEC2014	NEURONTIN	GABAPENTIN	OTHER NERVOUS SYSTEM DRUGS	Other: NEUROPATHIC PAIN (AE no. 03)	1800 mg	02Jul2015	17Dec2015		AE-3
		16SEP2014	19DEC2014	Pregabalin	PREGABALIN	PSYCHOLEPTICS	Pain-other	300 mg 2-0-2 a 75 mg	07Dec2016		Yes	
		16SEP2014	19DEC2014	Pregabalin	PREGABALIN	ANTIEPILEPTICS	Pain-other	300 mg 2-0-2 a 75 mg	07Dec2016		Yes	
		16SEP2014	19DEC2014	Pregabalin	PREGABALIN	ANALGESICS	Pain-other	300 mg 2-0-2 a 75 mg	07Dec2016		Yes	
		16SEP2014	19DEC2014	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-other (AE no. 05)	500 mg a 1-1-1/1500 mg	06Mar2017	Jul2019		AE-5
		16SEP2014	19DEC2014	Mefenam	MEFENAMIC ACID	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 06)	500 mg	Jul2017		Yes	AE-6
		16SEP2014	19DEC2014	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	15Sep2014	20Sep2014		
		16SEP2014	19DEC2014	CLAVAMOX	SPEKTRAMOX	ANTIBACTERIALS FOR SYSTEMIC USE	Other: COMMON COLD (AE no. 01)	2000 mg	18Feb2015	02Mar2015		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0123	ND plus	16SEP2014	19DEC2014	LYRICA	PREGABALIN	ANTIEPILEPTICS	Other: NEUROPATHIC PAIN (AE no. 03)	600 mg	17Dec2015	07Dec2016		AE-3
		16SEP2014	19DEC2014	LYRICA	PREGABALIN	PSYCHOLEPTICS	Other: NEUROPATHIC PAIN (AE no. 03)	600 mg	17Dec2015	07Dec2016		AE-3
		16SEP2014	19DEC2014	LYRICA	PREGABALIN	ANALGESICS	Other: NEUROPATHIC PAIN (AE no. 03)	600 mg	17Dec2015	07Dec2016		AE-3
		16SEP2014	19DEC2014	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombose prophylaxis (AE no. 05)	40 mg	06Mar2017	09Mar2017		AE-5
		16SEP2014	19DEC2014	Sirdalud	TIZANIDINE HYDROCHLORIDE	MUSCLE RELAXANTS	Pain-other (AE no. 05)	2 mg 0-0-1	06Mar2017	Jul2019		AE-5
		16SEP2014	19DEC2014	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Ulcera Prophylaxis	40 mg	15Sep2014	20Sep2014		
		16SEP2014	19DEC2014	LENDORM	BROTIZOLAM	PSYCHOLEPTICS	Other: INSOMNIA	0.25 mg	16Sep2014	19Sep2014		
		16SEP2014	19DEC2014	RHINON (Naphazolin, Hydrochlorid)	NAPHAZOLINE HYDROCHLORIDE	NASAL PREPARATIONS	Other: COMMON COLD (AE no. 01)	0.4 mg match 15 drops	18Feb2015	02Mar2015		AE-1
		16SEP2014	19DEC2014	RHINON (Naphazolin, Hydrochlorid)	NAPHAZOLINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Other: COMMON COLD (AE no. 01)	0.4 mg match 15 drops	18Feb2015	02Mar2015		AE-1
01/0124	ND plus	16SEP2014	19DEC2014	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Ulcus - prophylaxis (AE no. 05)	40 mg 1-0-0	06Mar2017		Yes	AE-5
		06NOV2014	-	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	01Oct2014	01Oct2014		
		06NOV2014	-	ITRACONAZOL	ITRACONAZOLE	ANTIMYCOTICS FOR SYSTEMIC USE	Other: EPIDERMOMYKOSIS (AE no. 01)	100 mg	01Oct2014	15Oct2014		AE-1
		06NOV2014	-	ALPRASTAD	ALPRAZOLAM	PSYCHOLEPTICS	Other: ANXIETY	0.5 mg	01Oct2014	01Oct2014		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0124	ND plus	06NOV2014	-	CIPRALEX	ESCITALOPRAM	PSYCHOANALEPTIC S	Other: DEPRESSION (AE no. 02)	10 mg	06Oct2014		Yes	AE-2
		06NOV2014	-	PEVARYL TOPICAL	ECONAZOLE	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: EPIDERMOMYKOSIS (AE no. 01)	1-2 x	01Oct2014	30Oct2014		AE-1
		06NOV2014	-	PEVARYL TOPICAL	ECONAZOLE	ANTIFUNGALS FOR DERMATOLOGICAL USE	Other: EPIDERMOMYKOSIS (AE no. 01)	1-2 x	01Oct2014	30Oct2014		AE-1
		06NOV2014	-	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	01Oct2014	01Oct2014		
		06NOV2014	-	MIRTAZAPIM	MIRTAZAPINE	PSYCHOANALEPTIC S	Other: DEPRESSION (AE no. 02)	30 mg	06Oct2014		Yes	AE-2
		06NOV2014	-	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	06Nov2014	06Nov2014		
		06NOV2014	-	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	06Nov2014	06Nov2014		
01/0125	SC	07OCT2014	-	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	06Oct2014	19Oct2014		
		07OCT2014	-	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	07Oct2014	07Oct2014		
		07OCT2014	-	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	07Oct2014	07Oct2014		
		07OCT2014	-	NEUROFENAC (Diclofenac-Natri um, Pyridoxin-Hydroch lorid, Thiamin-Nitrat)	B-VOLTAREN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: NERVE REGENERATION	150 mg	19Oct2014	05Nov2014		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0125	SC	07OCT2014	-	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	04Oct2014	12Oct2014		
01/0126	ND basic	08OCT2014	08JAN2015	Mycrogynon	EUGYNON /00022701/	SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	Other: Contraception	30 mg	UNK	Oct2017		
		08OCT2014	08JAN2015	Ciproxin	CIPROFLOXACIN	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Cystitis (AE no. 01)	1000 mg	07Oct2014	16Oct2014		AE-1
		08OCT2014	08JAN2015	Ciproxin	CIPROFLOXACIN	OTOLOGICALS	Other: Cystitis (AE no. 01)	1000 mg	07Oct2014	16Oct2014		AE-1
		08OCT2014	08JAN2015	Ciproxin	CIPROFLOXACIN	OPHTHALMOLOGICA LS	Other: Cystitis (AE no. 01)	1000 mg	07Oct2014	16Oct2014		AE-1
		08OCT2014	08JAN2015	Ciproxin	CIPROFLOXACIN	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: Cystitis (AE no. 01)	1000 mg	07Oct2014	16Oct2014		AE-1
		08OCT2014	08JAN2015	Ciproxin	CIPROFLOXACIN	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: Cystitis (AE no. 01)	1000 mg	07Oct2014	16Oct2014		AE-1
		08OCT2014	08JAN2015	Ciproxin	CIPROFLOXACIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Cystitis (AE no. 01)	1000 mg	07Oct2014	16Oct2014		AE-1
		08OCT2014	08JAN2015	Proxen (Naproxen)	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: Headache (AE no. 04)	500 mg	07Dec2014	07Dec2014		AE-4
		08OCT2014	08JAN2015	Proxen (Naproxen)	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: Headache (AE no. 04)	500 mg	07Dec2014	07Dec2014		AE-4

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0126	ND basic	08OCT2014	08JAN2015	Proxen (Naproxen)	NAPROXEN	OTHER GYNECOLOGICALS	Other: Headache (AE no. 04)	500 mg	07Dec2014	07Dec2014		AE-4
		08OCT2014	08JAN2015	Proxen (Naproxen)	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Other: Headache (AE no. 04)	500 mg	07Dec2014	07Dec2014		AE-4
		08OCT2014	08JAN2015	Proxen (Naproxen)	NAPROXEN	OPHTHALMOLOGICA LS	Other: Headache (AE no. 04)	500 mg	07Dec2014	07Dec2014		AE-4
		08OCT2014	08JAN2015	Proxen (Naproxen)	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Other: Headache (AE no. 05)	500 mg	14Jan2015	14Jan2015		AE-5
		08OCT2014	08JAN2015	Proxen (Naproxen)	NAPROXEN	OPHTHALMOLOGICA LS	Other: Headache (AE no. 05)	500 mg	14Jan2015	14Jan2015		AE-5
		08OCT2014	08JAN2015	Proxen (Naproxen)	NAPROXEN	OTHER GYNECOLOGICALS	Other: Headache (AE no. 05)	500 mg	14Jan2015	14Jan2015		AE-5
		08OCT2014	08JAN2015	Proxen (Naproxen)	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: Headache (AE no. 05)	500 mg	14Jan2015	14Jan2015		AE-5
		08OCT2014	08JAN2015	Proxen (Naproxen)	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: Headache (AE no. 05)	500 mg	14Jan2015	14Jan2015		AE-5
		08OCT2014	08JAN2015	BUSCAPINA	HYOSCINE BUTYLBROMIDE	DRUGS FOR FUNCTIONAL GASTROINTESTINA L DISORDERS	Other: ABDOMINAL CRAMPS (AE no. 08)	10 mg	12Mar2015	12Mar2015		AE-8
		08OCT2014	08JAN2015	DES Loratadin	DES Loratadin	ANTI H1 RECEPTOR ANTAGONISTS	Other: ERYTHEMA (AE no. 09)	5 mg	07May2015	11May2015		AE-9
		08OCT2014	08JAN2015	BUSCAPINA	HYOSCINE BUTYLBROMIDE	DRUGS FOR FUNCTIONAL GASTROINTESTINA L DISORDERS	Other: Flatulence (AE no. 11)	10 mg	09Oct2015	10Oct2015		AE-11

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0126	ND basic	08OCT2014	08JAN2015	JOSAMYCIN	JOSAMYCIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: respiratory tract infection (AE no. 13)	2 x 750 mg	Apr2018	Apr2018		AE-13
		08OCT2014	08JAN2015	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Ulcera Prohylaxis	40 mg	09Oct2014	06Nov2014		
		08OCT2014	08JAN2015	Magnosolv	MAGNOSOLV	MINERAL SUPPLEMENTS	Other: Cramps (AE no. 02)	6.1 g	09Oct2014	10Oct2014		AE-2
		08OCT2014	08JAN2015	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Ulcera Prophylaxis	40 mg	07Jan2015	05Feb2015		
		08OCT2014	08JAN2015	Pantoloc (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Ulcera Prophylaxis	40 mg if needed	14Feb2015		Yes	
		08OCT2014	08JAN2015	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	09Mar2015	09Mar2015		
		08OCT2014	08JAN2015	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	09Mar2015	09Mar2015		
		08OCT2014	08JAN2015	ADVANTAN	METHYLPREDNISOL ONE ACEPONATE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: ERYTHEMA (AE no. 09)	0.1% 1x	11May2015	03Jun2015		AE-9
		08OCT2014	08JAN2015	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 15)	400 mg	May2019	May2019		AE-15
		08OCT2014	08JAN2015	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 15)	400 mg	May2019	May2019		AE-15
		08OCT2014	08JAN2015	Antiflat	SIMETICONE	DRUGS FOR FUNCTIONAL GASTROINTESTINA L DISORDERS	Other: Flatulence (AE no. 11)	0.5 mg	09Oct2014	10Oct2014		AE-11

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0126	ND basic	08OCT2014	08JAN2015	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombosis Prophylaxis (AE no. 02)	40 mg	09Oct2014	14Oct2014		AE-2
		08OCT2014	08JAN2015	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: PAIN (AE no. 06)	400 mg if needed	16Jan2015	05Feb2015		AE-6
		08OCT2014	08JAN2015	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: PAIN (AE no. 06)	400 mg if needed	16Jan2015	05Feb2015		AE-6
		08OCT2014	08JAN2015	Effortil	ETILEFRINE HYDROCHLORIDE	CARDIAC THERAPY	Other: Circulation Problems (AE no. 03)	10 drops	10Oct2014	10Oct2014		AE-3
		08OCT2014	08JAN2015	Aspirin	ACETYLSALICYLIC ACID	ANTITHROMBOTIC AGENTS	Other: Headache (AE no. 04)	500 mg	07Dec2014	07Dec2014		AE-4
		08OCT2014	08JAN2015	Aspirin	ACETYLSALICYLIC ACID	STOMATOLOGICAL PREPARATIONS	Other: Headache (AE no. 04)	500 mg	07Dec2014	07Dec2014		AE-4
		08OCT2014	08JAN2015	Aspirin	ACETYLSALICYLIC ACID	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: Headache (AE no. 04)	500 mg	07Dec2014	07Dec2014		AE-4
		08OCT2014	08JAN2015	Aspirin	ACETYLSALICYLIC ACID	ANALGESICS	Other: Headache (AE no. 04)	500 mg	07Dec2014	07Dec2014		AE-4
		08OCT2014	08JAN2015	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombosis Prophylaxis (AE no. 07)	40 mg	09Jan2015	10Jan2015		AE-7
		08OCT2014	08JAN2015	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombosis Prophylaxis (AE no. 06)	40 mg	04Mar2015	13Mar2015		AE-6

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0127	ND plus	20OCT2014	09JAN2015	LENDORM	BROTIZOLAM	PSYCHOLEPTICS	Other: INSOMNIA PROPHYLAXIS	0.25 mg	23Oct2014	23Oct2014		
		20OCT2014	09JAN2015	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	10Jan2015	10Jan2015		
		20OCT2014	09JAN2015	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Radiculopathy (AE no. 02)	40 mg	27Jul2016	09Oct2016		AE-2
		20OCT2014	09JAN2015	Diprohos i.v.	DIPROSPAN /00582101/	CORTICOSTEROIDS DERMATOLOGICAL PREPARATIONS	Other: Radiculopathy (AE no. 02)	1 ml	07Oct2016	07Oct2016		AE-2
		20OCT2014	09JAN2015	Diprohos i.v.	DIPROSPAN /00582101/	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Radiculopathy (AE no. 02)	1 ml	07Oct2016	07Oct2016		AE-2
		20OCT2014	09JAN2015	Sirdalud	TIZANIDINE HYDROCHLORIDE	MUSCLE RELAXANTS	Other: Radiculopathy (AE no. 03)	2 mg	10Jul2017	Dec2019		AE-3
		20OCT2014	09JAN2015	Miranax 550 mg	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Other: Tooth removal (AE no. 05)	2 x 1	04Feb2018	08Feb2018		AE-5
		20OCT2014	09JAN2015	Miranax 550 mg	NAPROXEN	OPHTHALMOLOGICA LS	Other: Tooth removal (AE no. 05)	2 x 1	04Feb2018	08Feb2018		AE-5
		20OCT2014	09JAN2015	Miranax 550 mg	NAPROXEN	OTHER GYNECOLOGICALS	Other: Tooth removal (AE no. 05)	2 x 1	04Feb2018	08Feb2018		AE-5
		20OCT2014	09JAN2015	Miranax 550 mg	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: Tooth removal (AE no. 05)	2 x 1	04Feb2018	08Feb2018		AE-5
		20OCT2014	09JAN2015	Miranax 550 mg	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: Tooth removal (AE no. 05)	2 x 1	04Feb2018	08Feb2018		AE-5

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing? MH/AE	Assoc iated with MH/AE
01/0127	ND plus	20OCT2014	09JAN2015	Soludacortin 125 mg i.v.	PREDNISOLONE SODIUM SUCCINATE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Radiculopathy (AE no. 03)	125 mg	Jan2018	Jan2018		AE-3
		20OCT2014	09JAN2015	Soludacortin 125 mg i.v.	PREDNISOLONE SODIUM SUCCINATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Radiculopathy (AE no. 03)	125 mg	Jan2018	Jan2018		AE-3
		20OCT2014	09JAN2015	Soludacortin 125 mg i.v.	PREDNISOLONE SODIUM SUCCINATE	VASOPROTECTIVES	Other: Radiculopathy (AE no. 03)	125 mg	Jan2018	Jan2018		AE-3
		20OCT2014	09JAN2015	Soludacortin 125 mg i.v.	PREDNISOLONE SODIUM SUCCINATE	OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	Other: Radiculopathy (AE no. 03)	125 mg	Jan2018	Jan2018		AE-3
		20OCT2014	09JAN2015	Soludacortin 125 mg i.v.	PREDNISOLONE SODIUM SUCCINATE	OPHTHALMOLOGICALS	Other: Radiculopathy (AE no. 03)	125 mg	Jan2018	Jan2018		AE-3
		20OCT2014	09JAN2015	Soludacortin 125 mg i.v.	PREDNISOLONE SODIUM SUCCINATE	OTOLOGICALS	Other: Radiculopathy (AE no. 03)	125 mg	Jan2018	Jan2018		AE-3
		20OCT2014	09JAN2015	Volon A (Triamcinolon/Xyl ocaïn/Lidocain)	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICALS	Pain-other (AE no. 04)	10 mg/100 mg	02Mar2018	02Mar2018		AE-4
		20OCT2014	09JAN2015	Volon A (Triamcinolon/Xyl ocaïn/Lidocain)	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-other (AE no. 04)	10 mg/100 mg	02Mar2018	02Mar2018		AE-4
		20OCT2014	09JAN2015	Volon A (Triamcinolon/Xyl ocaïn/Lidocain)	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Pain-other (AE no. 04)	10 mg/100 mg	02Mar2018	02Mar2018		AE-4
		20OCT2014	09JAN2015	Volon A (Triamcinolon/Xyl ocaïn/Lidocain)	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Pain-other (AE no. 04)	10 mg/100 mg	02Mar2018	02Mar2018		AE-4
		20OCT2014	09JAN2015	Volon A (Triamcinolon/Xyl ocaïn/Lidocain)	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 04)	10 mg/100 mg	02Mar2018	02Mar2018		AE-4
		20OCT2014	09JAN2015	Volon A (Triamcinolon/Xyl ocaïn/Lidocain)	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 04)	10 mg/100 mg	02Mar2018	02Mar2018		AE-4

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0127	ND plus	20OCT2014	09JAN2015	Volon A (Triamcinolon/Xyl ocain/Lidocain)	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 04)	10 mg/100 mg	02Mar2018	02Mar2018		AE-4
		20OCT2014	09JAN2015	Neocitran (Ascorbic acid, Paracetamol, Pheniramin-Maleat , Phenylephrin-Hydr ochlorid)	NEO CITRAN /00438101/	ANALGESICS	Other (AE no. 08)		Jan2019	Jan2019		AE-8
		20OCT2014	09JAN2015	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	19Oct2014	24Oct2014		
		20OCT2014	09JAN2015	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	08Jan2015	10Jan2015		
		20OCT2014	09JAN2015	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: Radiculopathy (AE no. 02)	1200 mg/400 mg	27Jul2016	09Oct2016		AE-2
		20OCT2014	09JAN2015	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: Radiculopathy (AE no. 02)	1200 mg/400 mg	27Jul2016	09Oct2016		AE-2
		20OCT2014	09JAN2015	Diclobene i.v.	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Other: Radiculopathy (AE no. 02)	75 mg	09Oct2016	09Oct2016		AE-2
		20OCT2014	09JAN2015	Diclobene i.v.	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: Radiculopathy (AE no. 02)	75 mg	09Oct2016	09Oct2016		AE-2
		20OCT2014	09JAN2015	Diclobene i.v.	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: Radiculopathy (AE no. 02)	75 mg	09Oct2016	09Oct2016		AE-2
		20OCT2014	09JAN2015	Diclobene i.v.	DICLOFENAC SODIUM	THROAT PREPARATIONS	Other: Radiculopathy (AE no. 02)	75 mg	09Oct2016	09Oct2016		AE-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0127	ND plus	20OCT2014	09JAN2015	Diclobene i.v.	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Other: Radiculopathy (AE no. 02)	75 mg	09Oct2016	09Oct2016		AE-2
		20OCT2014	09JAN2015	Diclobene i.v.	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Other: Radiculopathy (AE no. 02)	75 mg	09Oct2016	09Oct2016		AE-2
		20OCT2014	09JAN2015	Diclofenac i.v.	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: Radiculopathy (AE no. 03)	1 amp a 75 mg	18Oct2017	18Oct2017		AE-3
		20OCT2014	09JAN2015	Diclofenac i.v.	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: Radiculopathy (AE no. 03)	1 amp a 75 mg	18Oct2017	18Oct2017		AE-3
		20OCT2014	09JAN2015	Diclofenac i.v.	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Other: Radiculopathy (AE no. 03)	1 amp a 75 mg	18Oct2017	18Oct2017		AE-3
		20OCT2014	09JAN2015	Diclofenac i.v.	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Other: Radiculopathy (AE no. 03)	1 amp a 75 mg	18Oct2017	18Oct2017		AE-3
		20OCT2014	09JAN2015	Diclofenac i.v.	DICLOFENAC	OPHTHALMOLOGICA LS	Other: Radiculopathy (AE no. 03)	1 amp a 75 mg	18Oct2017	18Oct2017		AE-3
		20OCT2014	09JAN2015	Diclofenac i.v.	DICLOFENAC	THROAT PREPARATIONS	Other: Radiculopathy (AE no. 03)	1 amp a 75 mg	18Oct2017	18Oct2017		AE-3
		20OCT2014	09JAN2015	Clindac Sandoz 300 mg	CLINDAMYCIN HYDROCHLORIDE	ANTI-ACNE PREPARATIONS	Other: Tooth removal (AE no. 05)	3 x 1	04Feb2018	08Feb2018		AE-5
		20OCT2014	09JAN2015	Clindac Sandoz 300 mg	CLINDAMYCIN HYDROCHLORIDE	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: Tooth removal (AE no. 05)	3 x 1	04Feb2018	08Feb2018		AE-5
		20OCT2014	09JAN2015	Clindac Sandoz 300 mg	CLINDAMYCIN HYDROCHLORIDE	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Tooth removal (AE no. 05)	3 x 1	04Feb2018	08Feb2018		AE-5
		20OCT2014	09JAN2015	Triamcinolon/Lido cain	MYKOPROCT N cain	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 04)	10 mg/100 mg	27Mar2018	27Mar2018		AE-4

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0127	ND plus	20OCT2014	09JAN2015	Triamcinolon/Lido cain	MYKOPROCT N	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 04)	10 mg/100 mg	27Mar2018	27Mar2018		AE-4
		20OCT2014	09JAN2015	Triamcinolon/Lido cain	MYKOPROCT N	VASOPROTECTIVES	Pain-other (AE no. 04)	10 mg/100 mg	27Mar2018	27Mar2018		AE-4
		20OCT2014	09JAN2015	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 03)	400 mg	10Jul2017	Dec2019		AE-3
		20OCT2014	09JAN2015	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 03)	400 mg	10Jul2017	Dec2019		AE-3
		20OCT2014	09JAN2015	CEFUIOXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	20Oct2014	20Oct2014		
		20OCT2014	09JAN2015	CEFUIOXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	20Oct2014	20Oct2014		
		20OCT2014	09JAN2015	AERIUS (DESLORATADIN)	DESLORATADINE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: POLLINOSIS (AE no. 01)	5 mg	01May2015	31May2015		AE-1
		20OCT2014	09JAN2015	Mexalen	PARACETAMOL	ANALGESICS	Other: Radiculopathy (AE no. 02)	2000 mg/500 mg	27Jul2016	09Oct2016		AE-2
		20OCT2014	09JAN2015	Diprophes i.v.	DIPROSPAN /00582101/	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Radiculopathy (AE no. 02)	1 ml	09Oct2016	09Oct2016		AE-2
		20OCT2014	09JAN2015	Diprophes i.v.	DIPROSPAN /00582101/	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Radiculopathy (AE no. 02)	1 ml	09Oct2016	09Oct2016		AE-2
		20OCT2014	09JAN2015	Novalgin 2.5 mg i.v.	METAMIZOLE SODIUM	ANALGESICS	Other: Radiculopathy (AE no. 03)	2.5 mg	18Oct2017	18Oct2017		AE-3
		20OCT2014	09JAN2015	Diclofenac i.v.	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Other: Radiculopathy (AE no. 03)	1 Amp a 75 mg	Jan2018	Jan2018		AE-3

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing? MH/AE	Assoc iated with MH/AE
01/0127	ND plus	20OCT2014	09JAN2015	Diclofenac i.v.	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: Radiculopathy (AE no. 03)	1 Amp a 75 mg	Jan2018	Jan2018		AE-3
		20OCT2014	09JAN2015	Diclofenac i.v.	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: Radiculopathy (AE no. 03)	1 Amp a 75 mg	Jan2018	Jan2018		AE-3
		20OCT2014	09JAN2015	Diclofenac i.v.	DICLOFENAC	OPHTHALMOLOGICA LS	Other: Radiculopathy (AE no. 03)	1 Amp a 75 mg	Jan2018	Jan2018		AE-3
		20OCT2014	09JAN2015	Diclofenac i.v.	DICLOFENAC	THROAT PREPARATIONS	Other: Radiculopathy (AE no. 03)	1 Amp a 75 mg	Jan2018	Jan2018		AE-3
		20OCT2014	09JAN2015	Diclofenac i.v.	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Other: Radiculopathy (AE no. 03)	1 Amp a 75 mg	Jan2018	Jan2018		AE-3
		20OCT2014	09JAN2015	Triamcinolon/Lido cain	MYKOPROCT N	VASOPROTECTIVES	Pain-other (AE no. 04)	10 mg/100 mg	23Apr2018	23Apr2018		AE-4
		20OCT2014	09JAN2015	Triamcinolon/Lido cain	MYKOPROCT N	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 04)	10 mg/100 mg	23Apr2018	23Apr2018		AE-4
		20OCT2014	09JAN2015	Triamcinolon/Lido cain	MYKOPROCT N	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 04)	10 mg/100 mg	23Apr2018	23Apr2018		AE-4
		20OCT2014	09JAN2015	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Ulcus prohylaxis (AE no. 03)	40 mg	10Jul2017	Dec2019		AE-3
		20OCT2014	09JAN2015	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	19Oct2014	29Nov2014		
		20OCT2014	09JAN2015	DES Lorantadin	DES Loratadine	ANTI H1STAMINES FOR SYSTEMIC USE	Other: POLLINOSIS (AE no. 01)	5 mg	01Jun2015	30Jun2015		AE-1
		20OCT2014	09JAN2015	Diclovene iv.	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: Radiculopathy (AE no. 02)	75 mg	07Oct2016	07Oct2016		AE-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0127	ND plus	20OCT2014	09JAN2015	Diclobene iv.	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: Radiculopathy (AE no. 02)	75 mg	07Oct2016	07Oct2016		AE-2
		20OCT2014	09JAN2015	Diclobene iv.	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Other: Radiculopathy (AE no. 02)	75 mg	07Oct2016	07Oct2016		AE-2
		20OCT2014	09JAN2015	Diclobene iv.	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Other: Radiculopathy (AE no. 02)	75 mg	07Oct2016	07Oct2016		AE-2
		20OCT2014	09JAN2015	Diclobene iv.	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Other: Radiculopathy (AE no. 02)	75 mg	07Oct2016	07Oct2016		AE-2
		20OCT2014	09JAN2015	Diclobene iv.	DICLOFENAC SODIUM	THROAT PREPARATIONS	Other: Radiculopathy (AE no. 02)	75 mg	07Oct2016	07Oct2016		AE-2
		20OCT2014	09JAN2015	Soludacortin 125 mg i.v.	PREDNISOLONE SODIUM SUCCINATE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Radiculopathy (AE no. 03)	125 mg	18Oct2017	18Oct2017		AE-3
		20OCT2014	09JAN2015	Soludacortin 125 mg i.v.	PREDNISOLONE SODIUM SUCCINATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Radiculopathy (AE no. 03)	125 mg	18Oct2017	18Oct2017		AE-3
		20OCT2014	09JAN2015	Soludacortin 125 mg i.v.	PREDNISOLONE SODIUM SUCCINATE	OTOLOGICALS	Other: Radiculopathy (AE no. 03)	125 mg	18Oct2017	18Oct2017		AE-3
		20OCT2014	09JAN2015	Soludacortin 125 mg i.v.	PREDNISOLONE SODIUM SUCCINATE	OPHTHALMOLOGICA LS	Other: Radiculopathy (AE no. 03)	125 mg	18Oct2017	18Oct2017		AE-3
		20OCT2014	09JAN2015	Soludacortin 125 mg i.v.	PREDNISOLONE SODIUM SUCCINATE	VASOPROTECTIVES	Other: Radiculopathy (AE no. 03)	125 mg	18Oct2017	18Oct2017		AE-3
		20OCT2014	09JAN2015	Soludacortin 125 mg i.v.	PREDNISOLONE SODIUM SUCCINATE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Radiculopathy (AE no. 03)	125 mg	18Oct2017	18Oct2017		AE-3
		20OCT2014	09JAN2015	Novalgine 2.5 mg i.v.	METAMIZOLE SODIUM	ANALGESICS	Other: Radiculopathy (AE no. 03)	2.5 mg	Jan2018	Jan2018		AE-3

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0127	ND plus	20OCT2014	09JAN2015	Ospen (Penicillin)	PHENOXYMETHYLPE NICILLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: root canal treatment (AE no. 07)	3 x 1500 mg	07May2018	16May2018		AE-7
		20OCT2014	09JAN2015	Mexalen	PARACETAMOL	ANALGESICS	Pain-other (AE no. 07)	unknown	09May2018	14May2018		AE-7
01/0128	ND plus	21OCT2014	13JAN2015	LENDORM	BROTIZOLAM	PSYCHOLEPTICS	Other: INSOMNIA PROPHYLAXIS	0.25 mg	20Oct2014	25Oct2014		
		21OCT2014	13JAN2015	AMOXICILLIN	AMOXICILLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: SINUSITIS (AE no. 01)	2000 mg	27Oct2014	04Nov2014		AE-1
		21OCT2014	13JAN2015	ANTIBIOTICS UNKNOWN	ANTIBIOTICS (90046601001)	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: COMMON COLD (AE no. 02)	UNK	25Nov2015	30Nov2015		AE-2
		21OCT2014	13JAN2015	ANTIBIOTICS UNKNOWN	ANTIBIOTICS (90046601001)	VASOPROTECTIVES	Other: COMMON COLD (AE no. 02)	UNK	25Nov2015	30Nov2015		AE-2
		21OCT2014	13JAN2015	ANTIBIOTICS UNKNOWN	ANTIBIOTICS (90046601001)	THROAT PREPARATIONS	Other: COMMON COLD (AE no. 02)	UNK	25Nov2015	30Nov2015		AE-2
		21OCT2014	13JAN2015	ANTIBIOTICS UNKNOWN	ANTIBIOTICS (90046601001)	OPHTHALMOLOGICA LS	Other: COMMON COLD (AE no. 02)	UNK	25Nov2015	30Nov2015		AE-2
		21OCT2014	13JAN2015	ANTIBIOTICS UNKNOWN	ANTIBIOTICS (90046601001)	ANTIMYCOTICS FOR SYSTEMIC USE	Other: COMMON COLD (AE no. 02)	UNK	25Nov2015	30Nov2015		AE-2
		21OCT2014	13JAN2015	ANTIBIOTICS UNKNOWN	ANTIBIOTICS (90046601001)	ANTIMYCOBACTERI ALS	Other: COMMON COLD (AE no. 02)	UNK	25Nov2015	30Nov2015		AE-2
		21OCT2014	13JAN2015	ANTIBIOTICS UNKNOWN	ANTIBIOTICS (90046601001)	ANTIBACTERIALS FOR SYSTEMIC USE	Other: COMMON COLD (AE no. 02)	UNK	25Nov2015	30Nov2015		AE-2
		21OCT2014	13JAN2015	ANTIBIOTICS UNKNOWN	ANTIBIOTICS (90046601001)	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: COMMON COLD (AE no. 02)	UNK	25Nov2015	30Nov2015		AE-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0128	ND plus	21OCT2014	13JAN2015	ANTIBIOTICS UNKNOWN	ANTIBIOTICS (90046601001)	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: COMMON COLD (AE no. 02)	UNK	25Nov2015	30Nov2015		AE-2
		21OCT2014	13JAN2015	ANTIBIOTICS UNKNOWN	ANTIBIOTICS (90046601001)	ANTIFUNGALS FOR DERMATOLOGICAL USE	Other: COMMON COLD (AE no. 02)	UNK	25Nov2015	30Nov2015		AE-2
		21OCT2014	13JAN2015	Xiclav (Amoxicillin + Clavulanic acid)	SPEKTRAMOX	ANTIBACTERIALS FOR SYSTEMIC USE	Other: BACTERIAL INFECTION (AE no. 03)	625 mg (500 mg + 125 mg)	10Jan2018	24Jan2018		AE-3
		21OCT2014	13JAN2015	Proxen (Naproxen)	NAPROXEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 04)	500 mg if needed	Nov2018	Dec2019		AE-4
		21OCT2014	13JAN2015	Proxen (Naproxen)	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 04)	500 mg if needed	Nov2018	Dec2019		AE-4
		21OCT2014	13JAN2015	Proxen (Naproxen)	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 04)	500 mg if needed	Nov2018	Dec2019		AE-4
		21OCT2014	13JAN2015	Proxen (Naproxen)	NAPROXEN	OPHTHALMOLOGICA LS	Pain-other (AE no. 04)	500 mg if needed	Nov2018	Dec2019		AE-4
		21OCT2014	13JAN2015	Proxen (Naproxen)	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 04)	500 mg if needed	Nov2018	Dec2019		AE-4
		21OCT2014	13JAN2015	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	06Oct2014	01Nov2014		
		21OCT2014	13JAN2015	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	22Oct2014	25Oct2014		
		21OCT2014	13JAN2015	ASPIRIN	ACETYLSALICYLIC ACID	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: SINUSITIS (AE no. 01)	1000 mg	04Nov2014	11Nov2014		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing? MH/AE	Assoc iated with MH/AE
01/0128	ND plus	21OCT2014	13JAN2015	ASPIRIN	ACETYLSALICYLIC ACID	ANALGESICS	Other: SINUSITIS (AE no. 01)	1000 mg	04Nov2014	11Nov2014		AE-1
		21OCT2014	13JAN2015	ASPIRIN	ACETYLSALICYLIC ACID	ANTITHROMBOTIC AGENTS	Other: SINUSITIS (AE no. 01)	1000 mg	04Nov2014	11Nov2014		AE-1
		21OCT2014	13JAN2015	ASPIRIN	ACETYLSALICYLIC ACID	STOMATOLOGICAL PREPARATIONS	Other: SINUSITIS (AE no. 01)	1000 mg	04Nov2014	11Nov2014		AE-1
		21OCT2014	13JAN2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 06)	600 mg if needed	Dec2018	Dec2019		AE-6
		21OCT2014	13JAN2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 06)	600 mg if needed	Dec2018	Dec2019		AE-6
		21OCT2014	13JAN2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 06)	600 mg if needed	Dec2018	Dec2019		AE-6
		21OCT2014	13JAN2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 06)	600 mg if needed	Dec2018	Dec2019		AE-6
		21OCT2014	13JAN2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 06)	600 mg if needed	Dec2018	Dec2019		AE-6
		21OCT2014	13JAN2015	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	21Oct2014	21Oct2014		
		21OCT2014	13JAN2015	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	21Oct2014	21Oct2014		
		21OCT2014	13JAN2015	NEOCITRAN (Paracetamol, Pheniramin Maleat, Phenylephrin Hydrochlorid, Ascorbinacid)	NEO CITRAN /00438101/	ANALGESICS	Other: SINUSITIS (AE no. 01)	1 Pack	11Nov2014	18Nov2014		AE-1
		21OCT2014	13JAN2015	LENDORM	BROTIZOLAM	PSYCHOLEPTICS	Other: INSOMNIA PROPHYLAXIS	0.25 mg	14Jan2015	14Jan2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0128	ND plus	21OCT2014	13JAN2015	NEUROBION FORTE (CYANOCOBALAMIN, PYRIDOXIN HYDROCHLORID, THIAMIN DISULFID)	VITAMEDIN INTRAVENOUS	VITAMINS	Other: NERVE REGENERATION	3 x per day	22Oct2014	12Nov2014		
		21OCT2014	13JAN2015	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	14Jan2015	14Jan2015		
01/0129	SC	29OCT2014	-	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	14Oct2014	15Nov2014		
		29OCT2014	-	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	29Oct2014	29Oct2014		
		29OCT2014	-	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	29Oct2014	29Oct2014		
		29OCT2014	-	Naropin 2 mg/ml	ROPIVACAINE HYDROCHLORIDE	ANESTHETICS	Other: Restenosis (AE no. 02)	3 ml	07Jul2017	07Jul2017		AE-2
		29OCT2014	-	Naropin 2 mg/ml	ROPIVACAINE HYDROCHLORIDE	ANESTHETICS	Other: Restenosis (AE no. 02)	3 ml	21Jul2017	21Jul2017		AE-2
		29OCT2014	-	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Ulcus prophylaxis (AE no. 04)	40 mg	18Mar2019	Mar2019		AE-4
		29OCT2014	-	NEUROBION FORTE (Cyanocobalamin Pyridocin Hydrochlorid Thiamin Disulfid)	VITAMEDIN INTRAVENOUS	VITAMINS	Other: NERVE REGENERATION	3 x 1	01Nov2014	UNK		
		29OCT2014	-	ANTIBIOTICS SANDOZ UNKNOWN	ANTIBIOTICS (90046601001)	ANTIMYCOBACTERI ALS	Other: BACT. INFECTION (AE no. 01)	UNK	15Oct2015	17Oct2015		AE-1
		29OCT2014	-	ANTIBIOTICS SANDOZ UNKNOWN	ANTIBIOTICS (90046601001)	ANTIMYCOTICS FOR SYSTEMIC USE	Other: BACT. INFECTION (AE no. 01)	UNK	15Oct2015	17Oct2015		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0129	SC	29OCT2014	-	ANTIBIOTICS SANDOZ UNKNOWN	ANTIBIOTICS (90046601001)	ANTIBACTERIALS FOR SYSTEMIC USE	Other: BACT. INFECTION (AE no. 01)	UNK	15Oct2015	17Oct2015		AE-1
		29OCT2014	-	ANTIBIOTICS SANDOZ UNKNOWN	ANTIBIOTICS (90046601001)	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: BACT. INFECTION (AE no. 01)	UNK	15Oct2015	17Oct2015		AE-1
		29OCT2014	-	ANTIBIOTICS SANDOZ UNKNOWN	ANTIBIOTICS (90046601001)	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: BACT. INFECTION (AE no. 01)	UNK	15Oct2015	17Oct2015		AE-1
		29OCT2014	-	ANTIBIOTICS SANDOZ UNKNOWN	ANTIBIOTICS (90046601001)	ANTIFUNGALS FOR DERMATOLOGICAL USE	Other: BACT. INFECTION (AE no. 01)	UNK	15Oct2015	17Oct2015		AE-1
		29OCT2014	-	ANTIBIOTICS SANDOZ UNKNOWN	ANTIBIOTICS (90046601001)	OPHTHALMOLOGICA LS	Other: BACT. INFECTION (AE no. 01)	UNK	15Oct2015	17Oct2015		AE-1
		29OCT2014	-	ANTIBIOTICS SANDOZ UNKNOWN	ANTIBIOTICS (90046601001)	THROAT PREPARATIONS	Other: BACT. INFECTION (AE no. 01)	UNK	15Oct2015	17Oct2015		AE-1
		29OCT2014	-	ANTIBIOTICS SANDOZ UNKNOWN	ANTIBIOTICS (90046601001)	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: BACT. INFECTION (AE no. 01)	UNK	15Oct2015	17Oct2015		AE-1
		29OCT2014	-	ANTIBIOTICS SANDOZ UNKNOWN	ANTIBIOTICS (90046601001)	VASOPROTECTIVES	Other: BACT. INFECTION (AE no. 01)	UNK	15Oct2015	17Oct2015		AE-1
		29OCT2014	-	Jopamiro 200 (Iopamidol)	IOPAMIDOL	CONTRAST MEDIA	Other: Restenosis (AE no. 02)	1 ml	07Jul2017	07Jul2017		AE-2
		29OCT2014	-	Jopamiro (Iopamidol)	IOPAMIDOL	CONTRAST MEDIA	Other: Restenosis (AE no. 02)	1 ml	21Jul2017	21Jul2017		AE-2
		29OCT2014	-	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-other (AE no. 04)	3 x 500 mg	18Mar2019	Apr2019		AE-4
		29OCT2014	-	LENDORM	BROTIZOLAM	PSYCHOLEPTICS	Other: INSOMNIA	0.25 mg	03Nov2014	04Nov2014		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0129	SC	29OCT2014	-	Noropin 2 mg/ml	ROPIVACAINE HYDROCHLORIDE	ANESTHETICS	Other: Restenosis (AE no. 02)	3 ml	14Jul2017	14Jul2017		AE-2
		29OCT2014	-	Seractil forte	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 04)	3 x 500 mg	18Mar2019	May2019		AE-4
		29OCT2014	-	Seractil forte	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 04)	3 x 500 mg	18Mar2019	May2019		AE-4
		29OCT2014	-	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	30Oct2014	05Nov2014		
		29OCT2014	-	Jopamiro 200 (Iopamidol)	IOPAMIDOL	CONTRAST MEDIA	Other: Restenosis (AE no. 02)	1 ml	14Jul2017	14Jul2017		AE-2
		29OCT2014	-	MEXALEN	PARACETAMOL	ANALGESICS	Pain-other (AE no. 05)	3 x 500 mg	May2019	Jun2019		AE-5
01/0130	ND basic	20NOV2014	03FEB2015	LENDORM	BROTIZOLAM	PSYCHOLEPTICS	Other: INSOMNIA PROPHYLAXIS	0.25 mg	19Nov2014	23Nov2014		
		20NOV2014	03FEB2015	Neocitran (Ascorbic acid, Paracetamol)	BIOGESIC /00411801/	ANALGESICS	Other: common cold (AE no. 02)	1500 mg	Feb2019	Feb2019		AE-2
		20NOV2014	03FEB2015	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	25Sep2014	27Nov2014		
		20NOV2014	03FEB2015	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	19Nov2014	23Nov2014		
		20NOV2014	03FEB2015	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other	400 mg if needed	01May2015		Yes	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0130	ND basic	20NOV2014	03FEB2015	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other	400 mg if needed	01May2015		Yes	
01/0131	ND plus	01DEC2014	19FEB2015	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Ulcera Prophylaxis	40 mg	24Nov2014	11Dec2014		
		01DEC2014	19FEB2015	Lendorm	BROTIZOLAM	PSYCHOLEPTICS	Other: Sleeping Induction	0.25 mg	29Nov2014	05Dec2014		
		01DEC2014	19FEB2015	Zithromax	AZITHROMYCIN	OPHTHALMOLOGICA LS	Other: antibiotic treatment due to bacterial infection (AE no. 04)	500 mg	Dec2019	Dec2019		AE-4
		01DEC2014	19FEB2015	Zithromax	AZITHROMYCIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic treatment due to bacterial infection (AE no. 04)	500 mg	Dec2019	Dec2019		AE-4
		01DEC2014	19FEB2015	Zithromax	AZITHROMYCIN	ANTI-ACNE PREPARATIONS	Other: antibiotic treatment due to bacterial infection (AE no. 04)	500 mg	Dec2019	Dec2019		AE-4
		01DEC2014	19FEB2015	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombosis Prophylaxis	40 mg	24Nov2014	05Dec2014		
		01DEC2014	19FEB2015	Aspirin	ACETYLSALICYLIC ACID	ANALGESICS	Pain-other (AE no. 05)	if needed (dose unknown)	Jan2019		Yes	AE-5
		01DEC2014	19FEB2015	Aspirin	ACETYLSALICYLIC ACID	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 05)	if needed (dose unknown)	Jan2019		Yes	AE-5

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0131	ND plus	01DEC2014	19FEB2015	Aspirin	ACETYLSALICYLIC ACID	ANTITHROMBOTIC AGENTS	Pain-other (AE no. 05)	if needed (dose unknown)	Jan2019		Yes	AE-5
		01DEC2014	19FEB2015	Aspirin	ACETYLSALICYLIC ACID	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 05)	if needed (dose unknown)	Jan2019		Yes	AE-5
		01DEC2014	19FEB2015	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: Infection Prophylaxis	1500 mg	01Dec2014	01Dec2014		
		01DEC2014	19FEB2015	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Infection Prophylaxis	1500 mg	01Dec2014	01Dec2014		
		01DEC2014	19FEB2015	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombosis Prophylaxis	40 mg	18Feb2015	20Feb2015		
01/0132	SC	02DEC2014	-	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	02Dec2014	02Dec2014		
		02DEC2014	-	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	02Dec2014	02Dec2014		
		02DEC2014	-	Amoxicillin	AMOXICILLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Sinusitis (AE no. 02)	1500 mg	Jun2017	Jun2017		AE-2
		02DEC2014	-	LENDORM	BROTIZOLAM	PSYCHOLEPTICS	Other: INSOMNIA PROPHYLACTIC	0.25 mg	02Dec2014	05Dec2014		
		02DEC2014	-	LAEVULAC	LACTULOSE	BILE AND LIVER THERAPY	Other: HAEMORRHOIDS (AE no. 01)	1 Spoon	08Dec2014	15Dec2014		AE-1
		02DEC2014	-	LAEVULAC	LACTULOSE	DRUGS FOR CONSTIPATION	Other: HAEMORRHOIDS (AE no. 01)	1 Spoon	08Dec2014	15Dec2014		AE-1
		02DEC2014	-	Mexalen 500 mg	PARACETAMOL	ANALGESICS	Other: Sinusitis (AE no. 02)	UN	Jun2017	Jun2017		AE-2
		02DEC2014	-	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	03Dec2014	05Dec2014		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0132	SC	02DEC2014	-	DICLOBENE	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 01)	100 mg if needed	08Dec2014	15Dec2014		AE-1
		02DEC2014	-	DICLOBENE	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain-other (AE no. 01)	100 mg if needed	08Dec2014	15Dec2014		AE-1
		02DEC2014	-	DICLOBENE	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain-other (AE no. 01)	100 mg if needed	08Dec2014	15Dec2014		AE-1
		02DEC2014	-	DICLOBENE	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 01)	100 mg if needed	08Dec2014	15Dec2014		AE-1
		02DEC2014	-	DICLOBENE	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 01)	100 mg if needed	08Dec2014	15Dec2014		AE-1
		02DEC2014	-	DICLOBENE	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 01)	100 mg if needed	08Dec2014	15Dec2014		AE-1
		02DEC2014	-	Clindamycin	CLINDAMYCIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: wisdom tooth removal (AE no. 04)	300 mg	06Dec2018	09Dec2018		AE-4
		02DEC2014	-	Clindamycin	CLINDAMYCIN	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: wisdom tooth removal (AE no. 04)	300 mg	06Dec2018	09Dec2018		AE-4
		02DEC2014	-	Clindamycin	CLINDAMYCIN	ANTI-ACNE PREPARATIONS	Other: wisdom tooth removal (AE no. 04)	300 mg	06Dec2018	09Dec2018		AE-4
		02DEC2014	-	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	01Dec2014	08Dec2014		
		02DEC2014	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 05)	600 mg	Sep2019	Nov2019		AE-5
		02DEC2014	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 05)	600 mg	Sep2019	Nov2019		AE-5
		02DEC2014	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 05)	600 mg	Sep2019	Nov2019		AE-5

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0132	SC	02DEC2014	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 05)	600 mg	Sep2019	Nov2019		AE-5
		02DEC2014	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 05)	600 mg	Sep2019	Nov2019		AE-5
01/0133	ND plus	16DEC2014	-	LENDORM	BROTIZOLAM	PSYCHOLEPTICS	Other: INSOMNIA	0.25 mg	15Dec2014	23Dec2014		
		16DEC2014	-	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	18Dec2014	23Dec2014		
		16DEC2014	-	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	17Dec2014		Yes	
		16DEC2014	-	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1000 mg	16Dec2014	16Dec2014		
		16DEC2014	-	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1000 mg	16Dec2014	16Dec2014		
01/0134	ND basic	17DEC2014	-	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	16Dec2014		Yes	
		17DEC2014	-	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	16Dec2014	21Dec2014		
		17DEC2014	-	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	17Dec2014	17Dec2014		
		17DEC2014	-	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	17Dec2014	17Dec2014		
		17DEC2014	-	LENDORM	BROTIZOLAM	PSYCHOLEPTICS	Other: INSOMNIA PROPHYLACTIC	0.25 mg	17Dec2014	17Dec2014		
01/0135	ND plus	15JAN2015	08APR2015	RAMIPRIL	RAMIPRIL	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Other: HYPERTENSION (MedHis no. 01)	2.5 mg	2012		Yes	MH-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0135	ND plus	15JAN2015	08APR2015	MEXALEN	PARACETAMOL	ANALGESICS	Other: COMMON COLD (AE no. 02)	1500 mg	20May2015	24May2015		AE-2
		15JAN2015	08APR2015	Proxen (Naproxen)	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: Lumbago (AE no. 03)	as needed	Dec2017	Jul2018		AE-3
		15JAN2015	08APR2015	Proxen (Naproxen)	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: Lumbago (AE no. 03)	as needed	Dec2017	Jul2018		AE-3
		15JAN2015	08APR2015	Proxen (Naproxen)	NAPROXEN	OTHER GYNECOLOGICALS	Other: Lumbago (AE no. 03)	as needed	Dec2017	Jul2018		AE-3
		15JAN2015	08APR2015	Proxen (Naproxen)	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Other: Lumbago (AE no. 03)	as needed	Dec2017	Jul2018		AE-3
		15JAN2015	08APR2015	Proxen (Naproxen)	NAPROXEN	OPHTHALMOLOGICA LS	Other: Lumbago (AE no. 03)	as needed	Dec2017	Jul2018		AE-3
		15JAN2015	08APR2015	Ciproxin	CIPROFLOXACIN	OTOLOGICALS	Other: respiratory tract infection (AE no. 04)	UNK	Jan2019	Jan2019		AE-4
		15JAN2015	08APR2015	Ciproxin	CIPROFLOXACIN	OPHTHALMOLOGICA LS	Other: respiratory tract infection (AE no. 04)	UNK	Jan2019	Jan2019		AE-4
		15JAN2015	08APR2015	Ciproxin	CIPROFLOXACIN	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: respiratory tract infection (AE no. 04)	UNK	Jan2019	Jan2019		AE-4
		15JAN2015	08APR2015	Ciproxin	CIPROFLOXACIN	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: respiratory tract infection (AE no. 04)	UNK	Jan2019	Jan2019		AE-4

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing? MH/AE	Assoc iated with MH/AE
01/0135	ND plus	15JAN2015	08APR2015	Ciproxin	CIPROFLOXACIN	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: respiratory tract infection (AE no. 04)	UNK	Jan2019	Jan2019		AE-4
		15JAN2015	08APR2015	Ciproxin	CIPROFLOXACIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: respiratory tract infection (AE no. 04)	UNK	Jan2019	Jan2019		AE-4
		15JAN2015	08APR2015	ZOLDEM	ZOLPIDEM TARTRATE	PSYCHOLEPTICS	Other: INSOMNIA PROPHYLACTIC	10 mg	14Jan2015	21Jan2015		
		15JAN2015	08APR2015	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	12Nov2014	Jul2017		
		15JAN2015	08APR2015	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: FEVER-INFECTION PROPHYLAXIS (AE no. 01)	4500 mg	16Jan2015	21Jan2015		AE-1
		15JAN2015	08APR2015	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: FEVER-INFECTION PROPHYLAXIS (AE no. 01)	4500 mg	16Jan2015	21Jan2015		AE-1
		15JAN2015	08APR2015	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	14Jan2015	21Jan2015		
01/0136	ND basic	23FEB2015	02JUN2015	ENALAPRIL	ENALAPRIL	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Other: HYPERTENSION (MedHis no. 02)	10 mg	2006	Jul2016		MH-2
		23FEB2015	02JUN2015	Volon 40 mg	TRIAMCINOLONE	STOMATOLOGICAL PREPARATIONS	Other: anti-inflammato ry drug as prophylaxis	40 mg	23Feb2015	23Feb2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0136	ND basic	23FEB2015	02JUN2015	Volon 40 mg	TRIAMCINOLONE	VASOPROTECTIVES	Other: anti-inflammato ry drug as prophylaxis	40 mg	23Feb2015	23Feb2015		
		23FEB2015	02JUN2015	Volon 40 mg	TRIAMCINOLONE	OPHTHALMOLOGICA LS	Other: anti-inflammato ry drug as prophylaxis	40 mg	23Feb2015	23Feb2015		
		23FEB2015	02JUN2015	Volon 40 mg	TRIAMCINOLONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: anti-inflammato ry drug as prophylaxis	40 mg	23Feb2015	23Feb2015		
		23FEB2015	02JUN2015	Volon 40 mg	TRIAMCINOLONE	NASAL PREPARATIONS	Other: anti-inflammato ry drug as prophylaxis	40 mg	23Feb2015	23Feb2015		
		23FEB2015	02JUN2015	Volon 40 mg	TRIAMCINOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: anti-inflammato ry drug as prophylaxis	40 mg	23Feb2015	23Feb2015		
		23FEB2015	02JUN2015	Volon 40 mg	TRIAMCINOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: anti-inflammato ry drug as prophylaxis	40 mg	23Feb2015	23Feb2015		
		23FEB2015	02JUN2015	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-other (AE no. 03)	500 mg if needed	Jul2017		Yes	AE-3
		23FEB2015	02JUN2015	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	01Dec2014	18Feb2015		
		23FEB2015	02JUN2015	ATORVASTATIN	ATORVASTATIN	LIPID MODIFYING AGENTS	Other: HYPERTENSION (MedHis no. 02)	10 mg	2006	Apr2018		MH-2
		23FEB2015	02JUN2015	LENDORM	BROTIZOLAM	PSYCHOLEPTICS	Other: INSOMNIA PROPHYLACTIC	0.25 mg	24Feb2015	25Feb2015		
		23FEB2015	02JUN2015	Atorvastatin	ATORVASTATIN	LIPID MODIFYING AGENTS	Other: HYPERTENSION (MedHis no. 02)	10 mg	Apr2018		Yes	MH-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0136	ND basic	23FEB2015	02JUN2015	EUTHYROX	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: HYPOTHYREOSIS (MedHis no. 01)	50 mg	2006		Yes	MH-1
		23FEB2015	02JUN2015	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	23Feb2015	23Feb2015		
		23FEB2015	02JUN2015	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	23Feb2015	23Feb2015		
		23FEB2015	02JUN2015	Heparin	HEPARIN	VASOPROTECTIVES	Other: Renal Infarction (AE no. 04)	5000 IU	19Feb2016	19Feb2016		AE-4
		23FEB2015	02JUN2015	Heparin	HEPARIN	ANTITHROMBOTIC AGENTS	Other: Renal Infarction (AE no. 04)	5000 IU	19Feb2016	19Feb2016		AE-4
		23FEB2015	02JUN2015	Heparin	HEPARIN	OPHTHALMOLOGICA LS	Other: Renal Infarction (AE no. 04)	5000 IU	19Feb2016	19Feb2016		AE-4
		23FEB2015	02JUN2015	NEBIVOLOL	NEBIVOLOL	BETA BLOCKING AGENTS	Other: HYPERTENSION (MedHis no. 02)	5 mg	2006		Yes	MH-2
		23FEB2015	02JUN2015	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	18Feb2015	26Feb2015		
		23FEB2015	02JUN2015	HIRUDOID forte GEL	MUCOPOLYSACCHAR IDE POLYSULFURIC ACID ESTER	EMOLLIENTS AND PROTECTIVES	Other: THROMBOSIS (AE no. 01)	2 x daily	07Apr2015	23Apr2015		AE-1
		23FEB2015	02JUN2015	HIRUDOID forte GEL	MUCOPOLYSACCHAR IDE POLYSULFURIC ACID ESTER	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: THROMBOSIS (AE no. 01)	2 x daily	07Apr2015	23Apr2015		AE-1
		23FEB2015	02JUN2015	HIRUDOID forte GEL	MUCOPOLYSACCHAR IDE POLYSULFURIC ACID ESTER	OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETA L SYSTEM	Other: THROMBOSIS (AE no. 01)	2 x daily	07Apr2015	23Apr2015		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0136	ND basic	23FEB2015	02JUN2015	HIRUDOID forte GEL	MUCOPOLYSACCHAR IDE POLYSULFURIC ACID ESTER	OPHTHALMOLOGICA LS	Other: THROMBOSIS (AE no. 01)	2 x daily	07Apr2015	23Apr2015		AE-1
		23FEB2015	02JUN2015	HIRUDOID forte GEL	MUCOPOLYSACCHAR IDE POLYSULFURIC ACID ESTER	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS (AE no. 01)	2 x daily	07Apr2015	23Apr2015		AE-1
		23FEB2015	02JUN2015	HIRUDOID forte GEL	MUCOPOLYSACCHAR IDE POLYSULFURIC ACID ESTER	VASOPROTECTIVES	Other: THROMBOSIS (AE no. 01)	2 x daily	07Apr2015	23Apr2015		AE-1
		23FEB2015	02JUN2015	Pradaxa	DABIGATRAN ETEXILATE MESILATE	ANTITHROMBOTIC AGENTS	Other: Thrombosis Prophylaxis (AE no. 04)	300 mg	Feb2016		Yes	AE-4
01/0137	ND plus	26FEB2015	02JUN2015	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	27Feb2015	18Mar2015		
		26FEB2015	02JUN2015	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	26Feb2015	26Feb2015		
		26FEB2015	02JUN2015	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	26Feb2015	26Feb2015		
		26FEB2015	02JUN2015	THYREX	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: multinodular goiter (AE no. 02)	50 MCG	20Jun2016		Yes	AE-2
		26FEB2015	02JUN2015	LENDORM	BROTIZOLAM	PSYCHOLEPTICS	Other: INSOMNIA PROPHYLACTIC	0.25 mg	26Feb2015	26Feb2015		
		26FEB2015	02JUN2015	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	25Feb2015	02Mar2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0138	SC	09MAR2015	-	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	08Mar2015	14Mar2015		
		09MAR2015	-	HALSET (CETYLPIRIDINUMCH LORID MONOHYDRAT)	CETYLPIRIDINIUM CHLORIDE	THROAT PREPARATIONS	Other: SORE THROAT (AE no. 01)	1.5 mg	10Mar2015	10Mar2015		AE-1
		09MAR2015	-	HALSET (CETYLPIRIDINUMCH LORID MONOHYDRAT)	CETYLPIRIDINIUM CHLORIDE	OPHTHALMOLOGICA LS	Other: SORE THROAT (AE no. 01)	1.5 mg	10Mar2015	10Mar2015		AE-1
		09MAR2015	-	HALSET (CETYLPIRIDINUMCH LORID MONOHYDRAT)	CETYLPIRIDINIUM CHLORIDE	STOMATOLOGICAL PREPARATIONS	Other: SORE THROAT (AE no. 01)	1.5 mg	10Mar2015	10Mar2015		AE-1
		09MAR2015	-	HALSET (CETYLPIRIDINUMCH LORID MONOHYDRAT)	CETYLPIRIDINIUM CHLORIDE	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: SORE THROAT (AE no. 01)	1.5 mg	10Mar2015	10Mar2015		AE-1
		09MAR2015	-	HALSET (CETYLPIRIDINUMCH LORID MONOHYDRAT)	CETYLPIRIDINIUM CHLORIDE	ANTISEPTICS AND DISINFECTANTS	Other: SORE THROAT (AE no. 01)	1.5 mg	10Mar2015	10Mar2015		AE-1
		09MAR2015	-	HALSET (CETYLPIRIDINUMCH LORID MONOHYDRAT)	CETYLPIRIDINIUM CHLORIDE	MEDICATED DRESSINGS	Other: SORE THROAT (AE no. 01)	1.5 mg	10Mar2015	10Mar2015		AE-1
		09MAR2015	-	CETIRIZIN	CETIRIZINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Other: POLLEN ALLERGY (AE no. 02)	10 mg	31Mar2015	31Mar2015		AE-2
		09MAR2015	-	CETIRIZIN	CETIRIZINE HYDROCHLORIDE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: POLLEN ALLERGY (AE no. 02)	10 mg	31Mar2015	31Mar2015		AE-2
		09MAR2015	-	PARACODIN	DIHYDROCODEINE	ANALGESICS	Other: COLD (AE no. 03)	1.5 ml	09Sep2015	13Sep2015		AE-3
		09MAR2015	-	MEXALEN	PARACETAMOL	ANALGESICS	Other: COLD (AE no. 04)	1000 mg	27Dec2015	02Jan2016		AE-4
		09MAR2015	-	Grippostad C	GRIPPOSTAD C	ANALGESICS	Other: Common Cold (AE no. 05)	2-2-2	31Dec2016	04Jan2017		AE-5

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0138	SC	09MAR2015	-	Seractil 400 mg	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: subluxation left ankle joint (AE no. 07)	400 mg if needed	20Jan2018		Yes	AE-7
		09MAR2015	-	Seractil 400 mg	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: subluxation left ankle joint (AE no. 07)	400 mg if needed	20Jan2018		Yes	AE-7
		09MAR2015	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Reflux (AE no. 09)	20 mg	23Jul2018	21Aug2018		AE-9
		09MAR2015	-	Grippostad C (Paracetamol 200 mg, Coffein 2.5 mg, Ascorbinacid 150 mg, Chlorphenaminhydr ogenmaleat 2.5 mg)	GRIPPOSTAD C	ANALGESICS	Other: Common Cold (AE no. 10)	6x/d	22Dec2019	26Dec2019		AE-10
		09MAR2015	-	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	08Mar2015	13Mar2015		
		09MAR2015	-	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	09Mar2015	09Mar2015		
		09MAR2015	-	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	09Mar2015	09Mar2015		
		09MAR2015	-	MEXALEN	PARACETAMOL	ANALGESICS	Other: COLD (AE no. 03)	1000 mg	09Sep2015	13Sep2015		AE-3
		09MAR2015	-	Sinupret	SINUPRET	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	Other: Common Cold (AE no. 05)	1-1-1	31Dec2016	04Jan2017		AE-5
		09MAR2015	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Reflux (AE no. 09)	40 mg	08Feb2019	28Feb2019		AE-9

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0138	SC	09MAR2015	-	TANTUM VERDE	BENZYDAMINE HYDROCHLORIDE	STOMATOLOGICAL PREPARATIONS	Other: SORE THROAT (AE no. 01)	9 mg	11Mar2015	19Mar2015		AE-1
		09MAR2015	-	TANTUM VERDE	BENZYDAMINE HYDROCHLORIDE	THROAT PREPARATIONS	Other: SORE THROAT (AE no. 01)	9 mg	11Mar2015	19Mar2015		AE-1
		09MAR2015	-	TANTUM VERDE	BENZYDAMINE HYDROCHLORIDE	OTHER GYNECOLOGICALS	Other: SORE THROAT (AE no. 01)	9 mg	11Mar2015	19Mar2015		AE-1
		09MAR2015	-	TANTUM VERDE	BENZYDAMINE HYDROCHLORIDE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: SORE THROAT (AE no. 01)	9 mg	11Mar2015	19Mar2015		AE-1
		09MAR2015	-	TANTUM VERDE	BENZYDAMINE HYDROCHLORIDE	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: SORE THROAT (AE no. 01)	9 mg	11Mar2015	19Mar2015		AE-1
		09MAR2015	-	AMBROXOL	AMBROXOL	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: COLD (AE no. 03)	120 mg	09Sep2015	14Sep2015		AE-3
		09MAR2015	-	AMBROXOL	AMBROXOL	COUGH AND COLD PREPARATIONS	Other: COLD (AE no. 03)	120 mg	09Sep2015	14Sep2015		AE-3
		09MAR2015	-	AMBROXOL	AMBROXOL	THROAT PREPARATIONS	Other: COLD (AE no. 03)	120 mg	09Sep2015	14Sep2015		AE-3
		09MAR2015	-	CETRIZIN	CETIRIZINE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: POLLINOSIS (AE no. 06)	10 mg	20Feb2016	22May2017		AE-6
		09MAR2015	-	CETRIZIN	CETIRIZINE	OPHTHALMOLOGICA LS	Other: POLLINOSIS (AE no. 06)	10 mg	20Feb2016	22May2017		AE-6
		09MAR2015	-	Cetirizin	CETIRIZINE	OPHTHALMOLOGICA LS	Other: Pollen Allergy (AE no. 06)	10 mg 1-0-0	20Feb2016	22May2017		AE-6
		09MAR2015	-	Cetirizin	CETIRIZINE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: Pollen Allergy (AE no. 06)	10 mg 1-0-0	20Feb2016	22May2017		AE-6
		09MAR2015	-	Cetirizin	CETIRIZINE HYDROCHLORIDE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: Pollen Allergy (AE no. 12)	10 mg	27Feb2019	16Apr2019		AE-12

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0138	SC	09MAR2015	-	Cetirizin	CETIRIZINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Other: Pollen Allergy (AE no. 12)	10 mg	27Feb2019	16Apr2019		AE-12
		09MAR2015	-	LENDORM	BROTIZOLAM	PSYCHOLEPTICS	Other: INSOMNIA PROPHYLACTIC	0.25 mg	09Mar2015	13Mar2015		
		09MAR2015	-	AERIUS (DESLORATADIN)	DESLORATADINE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: POLLEN ALLERGY (AE no. 02)	5 mg	15Mar2015	30Mar2015		AE-2
		09MAR2015	-	DOLO DOBEDAN	CEPACOL ANESTHETIC	THROAT PREPARATIONS	Other: COLD (AE no. 03)	2.8 mg	09Sep2015	14Sep2015		AE-3
		09MAR2015	-	DOLO DOBEDAN	CEPACOL ANESTHETIC	STOMATOLOGICAL PREPARATIONS	Other: COLD (AE no. 03)	2.8 mg	09Sep2015	14Sep2015		AE-3
		09MAR2015	-	DOLO DOBEDAN	CEPACOL ANESTHETIC	ANESTHETICS	Other: COLD (AE no. 03)	2.8 mg	09Sep2015	14Sep2015		AE-3
		09MAR2015	-	NASIVIN (Oxymetazolin Hydrochlorid)	OXYMETAZOLINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Other: COLD (AE no. 04)	3 x day	27Dec2015	02Jan2016		AE-4
		09MAR2015	-	NASIVIN (Oxymetazolin Hydrochlorid)	OXYMETAZOLINE HYDROCHLORIDE	NASAL PREPARATIONS	Other: COLD (AE no. 04)	3 x day	27Dec2015	02Jan2016		AE-4
		09MAR2015	-	NASIVIN (Oxymetazolin Hydrochlorid)	OXYMETAZOLINE HYDROCHLORIDE	OTHER DERMATOLOGICAL PREPARATIONS	Other: COLD (AE no. 04)	3 x day	27Dec2015	02Jan2016		AE-4
01/0139	ND plus	09MAR2015	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Reflux (AE no. 09)	40 mg	13Jul2019	31Aug2019		AE-9
		10MAR2015	03JUN2015	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	06Mar2015	03Apr2015		
		10MAR2015	03JUN2015	ONDANSETRON	ONDANSETRON	ANTIEMETICS AND ANTINAUSEANTS	Other: NAUSEA (AE no. 01)	4 mg/2 ml	10Mar2015	10Mar2015		AE-1
		10MAR2015	03JUN2015	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	10Mar2015	10Mar2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0139	ND plus	10MAR2015	03JUN2015	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	10Mar2015	10Mar2015		
		10MAR2015	03JUN2015	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	06Mar2015	14Mar2015		
01/0140	ND basic	12MAY2015	11AUG2015	Pantolac	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Prophylaxis (Ulcers)	40 mg	13May2015	03Jun2015		
		12MAY2015	11AUG2015	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	12Aug2015	12Aug2015		
		12MAY2015	11AUG2015	Sinupret intens, Gestion root, verbena, elder flower, sorrel herb, key flower blossoms	SINUPRET /07526101/	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	Other: COMMON COLD (AE no. 04)	1-1-1	Jun2017	Jun2017		AE-4
		12MAY2015	11AUG2015	Lendorm	BROTIZOLAM	PSYCHOLEPTICS	Other: Sleeping prophylaxis	0.25 mg	11May2015	14May2015		
		12MAY2015	11AUG2015	LENDORM	BROTIZOLAM	PSYCHOLEPTICS	Other: INSOMNIA PROPHYLACTIC	0.25 mg	10Aug2015	11Aug2015		
		12MAY2015	11AUG2015	Nasic xylometazolin + Dexpanthenol	NASIC	NASAL PREPARATIONS	Other: COMMON COLD (AE no. 04)	as needed	Jun2017	Jun2017		AE-4
		12MAY2015	11AUG2015	Nasic xylometazolin + Dexpanthenol	NASIC	OPHTHALMOLOGICA LS	Other: COMMON COLD (AE no. 04)	as needed	Jun2017	Jun2017		AE-4
		12MAY2015	11AUG2015	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombose prophylaxis	40 mg	11May2015	15May2015		
		12MAY2015	11AUG2015	CLINDAC	CLINDAMYCIN HYDROCHLORIDE	ANTIBACTERIALS FOR SYSTEMIC USE	Other: TOOTH ROOT TREATMENT (AE no. 03)	900 mg	22Sep2015	25Sep2015		AE-3

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0140	ND basic	12MAY2015	11AUG2015	CLINDAC	CLINDAMYCIN HYDROCHLORIDE	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: TOOTH ROOT TREATMENT (AE no. 03)	900 mg	22Sep2015	25Sep2015		AE-3
		12MAY2015	11AUG2015	CLINDAC	CLINDAMYCIN HYDROCHLORIDE	ANTI-ACNE PREPARATIONS	Other: TOOTH ROOT TREATMENT (AE no. 03)	900 mg	22Sep2015	25Sep2015		AE-3
		12MAY2015	11AUG2015	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: Infection Prophylaxis	1500 mg	12May2015	12May2015		
		12MAY2015	11AUG2015	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Infection Prophylaxis	1500 mg	12May2015	12May2015		
01/0141	SC	27MAY2015	-	Proxen (Naproxen)	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 04)	500 mg	Apr2019	Apr2019		AE-4
		27MAY2015	-	Proxen (Naproxen)	NAPROXEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 04)	500 mg	Apr2019	Apr2019		AE-4
		27MAY2015	-	Proxen (Naproxen)	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 04)	500 mg	Apr2019	Apr2019		AE-4
		27MAY2015	-	Proxen (Naproxen)	NAPROXEN	OPHTHALMOLOGICA LS	Pain-other (AE no. 04)	500 mg	Apr2019	Apr2019		AE-4
		27MAY2015	-	Proxen (Naproxen)	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 04)	500 mg	Apr2019	Apr2019		AE-4
		27MAY2015	-	Ibumetin	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 07)	600 mg	Feb2021	Feb2021		AE-7
		27MAY2015	-	Ibumetin	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 07)	600 mg	Feb2021	Feb2021		AE-7
		27MAY2015	-	Ibumetin	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 07)	600 mg	Feb2021	Feb2021		AE-7
		27MAY2015	-	Ibumetin	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 07)	600 mg	Feb2021	Feb2021		AE-7

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0141	SC	27MAY2015	-	Ibumetin	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 07)	600 mg	Feb2021	Feb2021		AE-7
		27MAY2015	-	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	26May2015	31May2015		
		27MAY2015	-	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Pain-other (AE no. 04)	40 mg	Apr2019	Apr2019		AE-4
		27MAY2015	-	PANTOPRAZOL	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	01May2015	03Jun2015		
		27MAY2015	-	CEFORUXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	27May2015	27May2015		
		27MAY2015	-	CEFORUXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	27May2015	27May2015		
		27MAY2015	-	Femibion 2 800 mg Folat	ASCORBIC ACID W/BIOTIN/COLECA LCIFEROL/DOCOSA H	ANTIANEMIC PREPARATIONS	Other: Pregnancy	800 mg	Feb2020	Sep2020		
01/0142	ND plus	27MAY2015	25AUG2015	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	20 mg	26May2015	04Jun2015		
		27MAY2015	25AUG2015	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	25Aug2015	26Aug2015		
		27MAY2015	25AUG2015	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 02)	800 mg	Jan2019	Feb2019		AE-2
		27MAY2015	25AUG2015	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 02)	800 mg	Jan2019	Feb2019		AE-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0142	ND plus	27MAY2015	25AUG2015	LENDORM	BROTIZOLAM	PSYCHOLEPTICS	Other: INSOMNIA PROPHYLACTIC	0.25 mg	27May2015	30May2015		
		27MAY2015	25AUG2015	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	26May2015	31May2015		
		27MAY2015	25AUG2015	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	27May2015	27May2015		
		27MAY2015	25AUG2015	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	27May2015	27May2015		
01/0143	ND plus	17JUN2015	22SEP2015	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	16Jun2015	27Jun2015		
		17JUN2015	22SEP2015	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	17Jun2015	17Jun2015		
		17JUN2015	22SEP2015	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	17Jun2015	17Jun2015		
		17JUN2015	22SEP2015	MEXALEN	PARACETAMOL	ANALGESICS	Pain-other (AE no. 03)	1500 mg	Jan2019	Jan2019		AE-3
		17JUN2015	22SEP2015	HALSET (CETYLPYRIDINUMCH LORID MONOHYDRAT)	CETYLPYRIDINIUM CHLORIDE	STOMATOLOGICAL PREPARATIONS	Other: SORE THROAT (AE no. 01)	1.5 mg if needed	19Jun2015	19Jun2015		AE-1
		17JUN2015	22SEP2015	HALSET (CETYLPYRIDINUMCH LORID MONOHYDRAT)	CETYLPYRIDINIUM CHLORIDE	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: SORE THROAT (AE no. 01)	1.5 mg if needed	19Jun2015	19Jun2015		AE-1
		17JUN2015	22SEP2015	HALSET (CETYLPYRIDINUMCH LORID MONOHYDRAT)	CETYLPYRIDINIUM CHLORIDE	OPHTHALMOLOGICA LS	Other: SORE THROAT (AE no. 01)	1.5 mg if needed	19Jun2015	19Jun2015		AE-1
		17JUN2015	22SEP2015	HALSET (CETYLPYRIDINUMCH LORID MONOHYDRAT)	CETYLPYRIDINIUM CHLORIDE	THROAT PREPARATIONS	Other: SORE THROAT (AE no. 01)	1.5 mg if needed	19Jun2015	19Jun2015		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0143	ND plus	17JUN2015	22SEP2015	HALSET (CETYLPYRIDINUMCH LORID MONOHYDRAT)	CETYLPYRIDINIUM CHLORIDE	MEDICATED DRESSINGS	Other: SORE THROAT (AE no. 01)	1.5 mg if needed	19Jun2015	19Jun2015		AE-1
		17JUN2015	22SEP2015	HALSET (CETYLPYRIDINUMCH LORID MONOHYDRAT)	CETYLPYRIDINIUM CHLORIDE	ANTISEPTICS AND DISINFECTANTS	Other: SORE THROAT (AE no. 01)	1.5 mg if needed	19Jun2015	19Jun2015		AE-1
		17JUN2015	22SEP2015	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	16Jun2015	20Jun2015		
01/0144	ND basic	24JUN2015	22SEP2015	METAMIZOLE	METAMIZOLE	ANALGESICS	Other: ULCERA PROPHYLAXIS	40 mg	22Jun2015	30Jun2015		
		24JUN2015	22SEP2015	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	25Jun2015	25Jun2015		
		24JUN2015	22SEP2015	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	25Jun2015	25Jun2015		
		24JUN2015	22SEP2015	AUGMENTIN (clavulanic acid+amoxicillin, 875mg/125mg)	AMOXI-CLAVULANI CO	ANTIBACTERIALS FOR SYSTEMIC USE	Other: acute pharyngitis (AE no. 03)	UNK	Apr2018	Apr2018		AE-3
		24JUN2015	22SEP2015	Xyloneural 1ml	LIDOCAINE HYDROCHLORIDE	UROLOGICALS	Pain-other (AE no. 04)	1ml local. nerve rootlet infil.	23May2020	23May2020		AE-4
		24JUN2015	22SEP2015	Xyloneural 1ml	LIDOCAINE HYDROCHLORIDE	ANTIPRURITICS, INCL. ANTI HISTAMINES, ANESTHETICS, ETC.	Pain-other (AE no. 04)	1ml local. nerve rootlet infil.	23May2020	23May2020		AE-4
		24JUN2015	22SEP2015	Xyloneural 1ml	LIDOCAINE HYDROCHLORIDE	ANESTHETICS	Pain-other (AE no. 04)	1ml local. nerve rootlet infil.	23May2020	23May2020		AE-4
		24JUN2015	22SEP2015	Xyloneural 1ml	LIDOCAINE HYDROCHLORIDE	OTOLOGICALS	Pain-other (AE no. 04)	1ml local. nerve rootlet infil.	23May2020	23May2020		AE-4
		24JUN2015	22SEP2015	Xyloneural 1ml	LIDOCAINE HYDROCHLORIDE	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 04)	1ml local. nerve rootlet infil.	23May2020	23May2020		AE-4

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing? MH/AE	Assoc iated with MH/AE
01/0144	ND basic	24JUN2015	22SEP2015	Xyloneural 1ml	LIDOCAINE HYDROCHLORIDE	VASOPROTECTIVES	Pain-other (AE no. 04)	1ml local. nerve rootlet infil.	23May2020	23May2020		AE-4
		24JUN2015	22SEP2015	Xyloneural 1ml	LIDOCAINE HYDROCHLORIDE	CARDIAC THERAPY	Pain-other (AE no. 04)	1ml local. nerve rootlet infil.	23May2020	23May2020		AE-4
		24JUN2015	22SEP2015	Xyloneural 1ml	LIDOCAINE HYDROCHLORIDE	THROAT PREPARATIONS	Pain-other (AE no. 04)	1ml local. nerve rootlet infil.	23May2020	23May2020		AE-4
		24JUN2015	22SEP2015	Xyloneural 1ml	LIDOCAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain-other (AE no. 04)	1ml local. nerve rootlet infil.	23May2020	23May2020		AE-4
		24JUN2015	22SEP2015	MEXALEN	PARACETAMOL	ANALGESICS	Pain-other (AE no. 02)	500 mg	21Sep2015	21Sep2015		AE-2
		24JUN2015	22SEP2015	FORTECORTIN	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 04)	3 x 4 mg	23Jan2019	27Jan2019		AE-4
		24JUN2015	22SEP2015	FORTECORTIN	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Pain-other (AE no. 04)	3 x 4 mg	23Jan2019	27Jan2019		AE-4
		24JUN2015	22SEP2015	FORTECORTIN	DEXAMETHASONE	CORTICOSTEROIDS / DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 04)	3 x 4 mg	23Jan2019	27Jan2019		AE-4
		24JUN2015	22SEP2015	FORTECORTIN	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Pain-other (AE no. 04)	3 x 4 mg	23Jan2019	27Jan2019		AE-4
		24JUN2015	22SEP2015	FORTECORTIN	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-other (AE no. 04)	3 x 4 mg	23Jan2019	27Jan2019		AE-4
		24JUN2015	22SEP2015	FORTECORTIN	DEXAMETHASONE	OPHTHALMOLOGICA LS	Pain-other (AE no. 04)	3 x 4 mg	23Jan2019	27Jan2019		AE-4
		24JUN2015	22SEP2015	FORTECORTIN	DEXAMETHASONE	NASAL PREPARATIONS	Pain-other (AE no. 04)	3 x 4 mg	23Jan2019	27Jan2019		AE-4
		24JUN2015	22SEP2015	FORTECORTIN	DEXAMETHASONE	VASOPROTECTIVES	Pain-other (AE no. 04)	3 x 4 mg	23Jan2019	27Jan2019		AE-4
		24JUN2015	22SEP2015	FORTECORTIN	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 04)	3 x 4 mg	23Jan2019	27Jan2019		AE-4
		24JUN2015	22SEP2015	FORTECORTIN	DEXAMETHASONE	OTOLOGICALS	Pain-other (AE no. 04)	3 x 4 mg	23Jan2019	27Jan2019		AE-4

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0144	ND basic	24JUN2015	22SEP2015	FORTECORTIN	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Pain-other (AE no. 04)	3 x 4 mg	23Jan2019	27Jan2019		AE-4
		24JUN2015	22SEP2015	Dexabene 4 mg	DEXAMETHASONE SODIUM PHOSPHATE	OPHTHALMOLOGICA LS	Pain-other (AE no. 04)	4mg local. nerve rootlet infil.	23May2020	23May2020		AE-4
		24JUN2015	22SEP2015	Dexabene 4 mg	DEXAMETHASONE SODIUM PHOSPHATE	NASAL PREPARATIONS	Pain-other (AE no. 04)	4mg local. nerve rootlet infil.	23May2020	23May2020		AE-4
		24JUN2015	22SEP2015	Dexabene 4 mg	DEXAMETHASONE SODIUM PHOSPHATE	VASOPROTECTIVES	Pain-other (AE no. 04)	4mg local. nerve rootlet infil.	23May2020	23May2020		AE-4
		24JUN2015	22SEP2015	Dexabene 4 mg	DEXAMETHASONE SODIUM PHOSPHATE	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 04)	4mg local. nerve rootlet infil.	23May2020	23May2020		AE-4
		24JUN2015	22SEP2015	Dexabene 4 mg	DEXAMETHASONE SODIUM PHOSPHATE	OTOLOGICALS	Pain-other (AE no. 04)	4mg local. nerve rootlet infil.	23May2020	23May2020		AE-4
		24JUN2015	22SEP2015	Dexabene 4 mg	DEXAMETHASONE SODIUM PHOSPHATE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Pain-other (AE no. 04)	4mg local. nerve rootlet infil.	23May2020	23May2020		AE-4
		24JUN2015	22SEP2015	Dexabene 4 mg	DEXAMETHASONE SODIUM PHOSPHATE	ANTI-ACNE PREPARATIONS	Pain-other (AE no. 04)	4mg local. nerve rootlet infil.	23May2020	23May2020		AE-4
		24JUN2015	22SEP2015	Dexabene 4 mg	DEXAMETHASONE SODIUM PHOSPHATE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 04)	4mg local. nerve rootlet infil.	23May2020	23May2020		AE-4
		24JUN2015	22SEP2015	Dexabene 4 mg	DEXAMETHASONE SODIUM PHOSPHATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 04)	4mg local. nerve rootlet infil.	23May2020	23May2020		AE-4
		24JUN2015	22SEP2015	PARKEMED	MEFENAMIC ACID	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 02)	500 mg	21Sep2015	21Sep2015		AE-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0144	ND basic	24JUN2015	22SEP2015	NEODOLPASSE (Diclofenac 75 mg, Orphenadricin 30 mg)	NEODOLPASSE	MUSCLE RELAXANTS	Pain-other (AE no. 04)	10 x 250 ml in 3 months	25Jan2019	Apr2019		AE-4
		24JUN2015	22SEP2015	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	24Jun2015	28Jun2015		
		24JUN2015	22SEP2015	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 04)	UNK	Nov2018	May2019		AE-4
		24JUN2015	22SEP2015	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 04)	UNK	Nov2018	May2019		AE-4
01/0145	ND plus	16JUL2015	07OCT2015	SYMBICORT	BUDESONIDE W/FORMOTEROL FUMARATE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: ASTHMA	2x/day	UNK		Yes	
		16JUL2015	07OCT2015	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	05Oct2015	07Oct2015		
		16JUL2015	07OCT2015	VOLONA INFILTRATION (TRIAMCINOLON ACETONID)	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS / DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 02)	40 mg	02Oct2015	02Oct2015		AE-2
		16JUL2015	07OCT2015	VOLONA INFILTRATION (TRIAMCINOLON ACETONID)	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 02)	40 mg	02Oct2015	02Oct2015		AE-2
		16JUL2015	07OCT2015	VOLONA INFILTRATION (TRIAMCINOLON ACETONID)	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICA LS	Pain-other (AE no. 02)	40 mg	02Oct2015	02Oct2015		AE-2
		16JUL2015	07OCT2015	VOLONA INFILTRATION (TRIAMCINOLON ACETONID)	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-other (AE no. 02)	40 mg	02Oct2015	02Oct2015		AE-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0145	ND plus	16JUL2015	07OCT2015	VOLONA INFILTRATION (TRIAMCINOLON ACETONID)	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Pain-other (AE no. 02)	40 mg	02Oct2015	02Oct2015		AE-2
		16JUL2015	07OCT2015	VOLONA INFILTRATION (TRIAMCINOLON ACETONID)	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 02)	40 mg	02Oct2015	02Oct2015		AE-2
		16JUL2015	07OCT2015	VOLONA INFILTRATION (TRIAMCINOLON ACETONID)	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Pain-other (AE no. 02)	40 mg	02Oct2015	02Oct2015		AE-2
		16JUL2015	07OCT2015	Cotrimoxazol = Trimethoprim + Sulfamethoxazol	BACTRIM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Urinary tract infection (AE no. 05)	400 mg/80 mg	Jun2017	Jun2017		AE-5
		16JUL2015	07OCT2015	Mevir (Brivudin)	BRIVUDINE	ANTIVIRALS FOR SYSTEMIC USE	Other: Herpes zoster (AE no. 07)	125 mg	19Mar2018	27Mar2018		AE-7
		16JUL2015	07OCT2015	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 02)	800 mg	Dec2019	Dec2019		AE-2
		16JUL2015	07OCT2015	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 02)	800 mg	Dec2019	Dec2019		AE-2
		16JUL2015	07OCT2015	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	14Jul2015	25Jul2015		
		16JUL2015	07OCT2015	CIPROXIN	CIPROFLOXACIN	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: CYSTITIS (AE no. 01)	1000 mg	19Jul2015	21Jul2015		AE-1
		16JUL2015	07OCT2015	CIPROXIN	CIPROFLOXACIN	OTOLOGICALS	Other: CYSTITIS (AE no. 01)	1000 mg	19Jul2015	21Jul2015		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0145	ND plus	16JUL2015	07OCT2015	CIPROXIN	CIPROFLOXACIN	OPHTHALMOLOGICA LS	Other: CYSTITIS (AE no. 01)	1000 mg	19Jul2015	21Jul2015		AE-1
		16JUL2015	07OCT2015	CIPROXIN	CIPROFLOXACIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: CYSTITIS (AE no. 01)	1000 mg	19Jul2015	21Jul2015		AE-1
		16JUL2015	07OCT2015	CIPROXIN	CIPROFLOXACIN	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: CYSTITIS (AE no. 01)	1000 mg	19Jul2015	21Jul2015		AE-1
		16JUL2015	07OCT2015	CIPROXIN	CIPROFLOXACIN	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: CYSTITIS (AE no. 01)	1000 mg	19Jul2015	21Jul2015		AE-1
		16JUL2015	07OCT2015	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: SALPINGITIS (AE no. 03)	400 mg	17Nov2015	23Nov2015		AE-3
		16JUL2015	07OCT2015	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: SALPINGITIS (AE no. 03)	400 mg	17Nov2015	23Nov2015		AE-3
		16JUL2015	07OCT2015	SERACTIL FORTE	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: CERVICALGIA (AE no. 04)	800 mg	20Dec2015		Yes	AE-4
		16JUL2015	07OCT2015	SERACTIL FORTE	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: CERVICALGIA (AE no. 04)	800 mg	20Dec2015		Yes	AE-4
		16JUL2015	07OCT2015	Ciproxin (Ciprofloxacin)	CIPROFLOXACIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Urinary tract infection (AE no. 08)	250 mg 1-0-1	03Aug2018	09Aug2018		AE-8

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0145	ND plus	16JUL2015	07OCT2015	Ciproxin (Ciprofloxacin)	CIPROFLOXACIN	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: Urinary tract infection (AE no. 08)	250 mg 1-0-1	03Aug2018	09Aug2018		AE-8
		16JUL2015	07OCT2015	Ciproxin (Ciprofloxacin)	CIPROFLOXACIN	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: Urinary tract infection (AE no. 08)	250 mg 1-0-1	03Aug2018	09Aug2018		AE-8
		16JUL2015	07OCT2015	Ciproxin (Ciprofloxacin)	CIPROFLOXACIN	OTOLOGICALS	Other: Urinary tract infection (AE no. 08)	250 mg 1-0-1	03Aug2018	09Aug2018		AE-8
		16JUL2015	07OCT2015	Ciproxin (Ciprofloxacin)	CIPROFLOXACIN	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Urinary tract infection (AE no. 08)	250 mg 1-0-1	03Aug2018	09Aug2018		AE-8
		16JUL2015	07OCT2015	Ciproxin (Ciprofloxacin)	CIPROFLOXACIN	OPHTHALMOLOGICA LS	Other: Urinary tract infection (AE no. 08)	250 mg 1-0-1	03Aug2018	09Aug2018		AE-8
		16JUL2015	07OCT2015	Clavamox	SPEKTRAMOX	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic drug (AE no. 11)	1000 mg x 2	29Sep2020	03Oct2020		AE-11
		16JUL2015	07OCT2015	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	15Jul2015	19Jul2015		
		16JUL2015	07OCT2015	FLOXACIN (NORFLOXACIN)	NORFLOXACIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: SALPINGITIS (AE no. 03)	800 mg	17Nov2015	23Nov2015		AE-3
		16JUL2015	07OCT2015	FLOXACIN (NORFLOXACIN)	NORFLOXACIN	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: SALPINGITIS (AE no. 03)	800 mg	17Nov2015	23Nov2015		AE-3

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0145	ND plus	16JUL2015	07OCT2015	FLOXACIN (NORFLOXACIN)	NORFLOXACIN	OPHTHALMOLOGICA LS	Other: SALPINGITIS (AE no. 03)	800 mg	17Nov2015	23Nov2015		AE-3
		16JUL2015	07OCT2015	SIRDALUD	TIZANIDINE HYDROCHLORIDE	MUSCLE RELAXANTS	Other: CERVICALGIA (AE no. 04)	4 mg (if needed)	20Dec2015		Yes	AE-4
		16JUL2015	07OCT2015	Mevir (Brivudin)	BRIVUDINE	ANTIVIRALS FOR SYSTEMIC USE	Other: Herpes zoster (AE no. 06)	125 mg	Dec2017	Dec2017		AE-6
		16JUL2015	07OCT2015	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	16Jul2015	16Jul2015		
		16JUL2015	07OCT2015	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	16Jul2015	16Jul2015		
		16JUL2015	07OCT2015	BUCAIN 0.25% INFILTRATION	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain-other (AE no. 02)	2 ml	02Oct2015	02Oct2015		AE-2
		16JUL2015	07OCT2015	BUCAIN 0.25% INFILTRATION	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain-other (AE no. 02)	2 ml	02Oct2015	02Oct2015		AE-2
		16JUL2015	07OCT2015	Auclobene	ACICLOVIR	ANTIVIRALS FOR SYSTEMIC USE	Other: Herpes zoster (AE no. 09)	4000 mg	Sep2019	Sep2019		AE-9
		16JUL2015	07OCT2015	Auclobene	ACICLOVIR	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: Herpes zoster (AE no. 09)	4000 mg	Sep2019	Sep2019		AE-9
		16JUL2015	07OCT2015	Auclobene	ACICLOVIR	OPHTHALMOLOGICA LS	Other: Herpes zoster (AE no. 09)	4000 mg	Sep2019	Sep2019		AE-9
01/0146	SC	16JUL2015	-	AMLODIPIN	AMLODIPINE	CALCIUM CHANNEL BLOCKERS	Other: HYPERTENSION (MedHis no. 01)	5 mg	2010		Yes	MH-1
		16JUL2015	-	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	18Jul2015	01Aug2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0146	SC	16JUL2015	-	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	17Jul2015	19Jul2015		
		16JUL2015	-	Lyrica	PREGABALIN	ANALGESICS	Other: neuropathic pain (MedHis no. 03)	200 mg	01Dec2019		Yes	MH-3
		16JUL2015	-	Lyrica	PREGABALIN	PSYCHOLEPTICS	Other: neuropathic pain (MedHis no. 03)	200 mg	01Dec2019		Yes	MH-3
		16JUL2015	-	Lyrica	PREGABALIN	ANTIEPILEPTICS	Other: neuropathic pain (MedHis no. 03)	200 mg	01Dec2019		Yes	MH-3
		16JUL2015	-	VENLAFAB	VENLAFAXINE HYDROCHLORIDE	ANALGESICS	Other: DEPRESSION (MedHis no. 02)	75 mg	2010		Yes	MH-2
		16JUL2015	-	VENLAFAB	VENLAFAXINE HYDROCHLORIDE	PSYCHOANALEPTIC S	Other: DEPRESSION (MedHis no. 02)	75 mg	2010		Yes	MH-2
		16JUL2015	-	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: ULCERA PROPHYLAXIS	1500 mg	16Jul2015	16Jul2015		
		16JUL2015	-	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: ULCERA PROPHYLAXIS	1500 mg	16Jul2015	16Jul2015		
		16JUL2015	-	TRITTICO	TRAZODONE HYDROCHLORIDE	PSYCHOANALEPTIC S	Other: DEPRESSION (MedHis no. 02)	15 mg	2010		Yes	MH-2
		16JUL2015	-	SIFROL	PRAMIPEXOLE DIHYDROCHLORIDE	ANTI-PARKINSON DRUGS	Other: DEPRESSION (MedHis no. 02)	0.088 mg	2010	30Nov2019		MH-2
01/0147	ND plus	20AUG2015	18NOV2015	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	20Aug2015	03Sep2015		
		20AUG2015	18NOV2015	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	17Aug2015	24Aug2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0147	ND plus	20AUG2015	18NOV2015	ACC HEXAL (ACETYLCYSTEIN)	ACETYLCYSTEINE	COUGH AND COLD PREPARATIONS	Other: COLD (AE no. 01)	600 mg	22Oct2015	24Oct2015		AE-1
		20AUG2015	18NOV2015	ACC HEXAL (ACETYLCYSTEIN)	ACETYLCYSTEINE	OPHTHALMOLOGICA LS	Other: COLD (AE no. 01)	600 mg	22Oct2015	24Oct2015		AE-1
		20AUG2015	18NOV2015	ACC HEXAL (ACETYLCYSTEIN)	ACETYLCYSTEINE	NASAL PREPARATIONS	Other: COLD (AE no. 01)	600 mg	22Oct2015	24Oct2015		AE-1
		20AUG2015	18NOV2015	ACC HEXAL (ACETYLCYSTEIN)	ACETYLCYSTEINE	OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	Other: COLD (AE no. 01)	600 mg	22Oct2015	24Oct2015		AE-1
		20AUG2015	18NOV2015	ACC HEXAL (ACETYLCYSTEIN)	ACETYLCYSTEINE	ALL OTHER THERAPEUTIC PRODUCTS	Other: COLD (AE no. 01)	600 mg	22Oct2015	24Oct2015		AE-1
		20AUG2015	18NOV2015	WICK HUSTENLÖSER (GUAIFENESIN)	GUAIFENESIN	COUGH AND COLD PREPARATIONS	Other: COLD (AE no. 02)	45 ml	26Nov2015	30Nov2015		AE-2
		20AUG2015	18NOV2015	Mexalen	PARACETAMOL	ANALGESICS	Other: COLD (AE no. 04)	1000 mg	31Oct2016	07Nov2016		AE-4
		20AUG2015	18NOV2015	Triprim (trimethoprim)	TRIMETHOPRIM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Urinary tract infection (AE no. 05)	300 mg 0-1-0	24May2017	26May2017		AE-5
		20AUG2015	18NOV2015	WICK HUSTENLÖSER (GUAIFENESIN)	GUAIFENESIN	COUGH AND COLD PREPARATIONS	Other: Bronchitis (AE no. 07)	200 mg 1-1-1	06Jun2017	09Jun2017		AE-7
		20AUG2015	18NOV2015	Mucosolvan	AMBROXOL HYDROCHLORIDE	COUGH AND COLD PREPARATIONS	Other: AE 09 common cold (AE no. 09)	UNK	12Feb2018	16Feb2018		AE-9
		20AUG2015	18NOV2015	Mucosolvan	AMBROXOL HYDROCHLORIDE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: AE 09 common cold (AE no. 09)	UNK	12Feb2018	16Feb2018		AE-9
		20AUG2015	18NOV2015	Mucosolvan	AMBROXOL HYDROCHLORIDE	THROAT PREPARATIONS	Other: AE 09 common cold (AE no. 09)	UNK	12Feb2018	16Feb2018		AE-9

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0147	ND plus	20AUG2015	18NOV2015	Cough syrup (30 mg Ambroxol hydrochloride, Benzoic acid, sorbitol solution, hydroxyethyl cellulose)	MUCOLYTICS (90040101001)	COUGH AND COLD PREPARATIONS	Other: AE 07 common cold (AE no. 07)	200 mg 3x/d	06Jun2017	09Jun2017		AE-7
		20AUG2015	18NOV2015	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICALS	Other: INFECTION PROPHYLAXIS	1500 mg	20Aug2015	20Aug2015		
		20AUG2015	18NOV2015	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	20Aug2015	20Aug2015		
		20AUG2015	18NOV2015	MEXALEN	PARACETAMOL	ANALGESICS	Other: COLD (AE no. 01)	1000 mg	30Oct2015	01Nov2015		AE-1
		20AUG2015	18NOV2015	MEXALEN	PARACETAMOL	ANALGESICS	Other: COLD (AE no. 02)	1000 mg	26Nov2015	30Nov2015		AE-2
		20AUG2015	18NOV2015	Naproxen	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 03)	1000 mg	05Sep2016	12Sep2016		AE-3
		20AUG2015	18NOV2015	Naproxen	NAPROXEN	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 03)	1000 mg	05Sep2016	12Sep2016		AE-3
		20AUG2015	18NOV2015	Naproxen	NAPROXEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 03)	1000 mg	05Sep2016	12Sep2016		AE-3
		20AUG2015	18NOV2015	Naproxen	NAPROXEN	OPHTHALMOLOGICALS	Pain-other (AE no. 03)	1000 mg	05Sep2016	12Sep2016		AE-3
		20AUG2015	18NOV2015	Naproxen	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 03)	1000 mg	05Sep2016	12Sep2016		AE-3
		20AUG2015	18NOV2015	Mexalen (Paracetamol)	PARACETAMOL	ANALGESICS	Pain-other (AE no. 06)	500 mg x4 1-1-1-1	17Apr2017	28Apr2017		AE-6
		20AUG2015	18NOV2015	Mucosolvan	AMBROXOL HYDROCHLORIDE	COUGH AND COLD PREPARATIONS	Other: AE 07 common cold (AE no. 07)	100 mg 3x/d	12Jun2017	15Jun2017		AE-7

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0147	ND plus	20AUG2015	18NOV2015	Mucosolvan	AMBROXOL HYDROCHLORIDE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: AE 07 common cold (AE no. 07)	100 mg 3x/d	12Jun2017	15Jun2017		AE-7
		20AUG2015	18NOV2015	Mucosolvan	AMBROXOL HYDROCHLORIDE	THROAT PREPARATIONS	Other: AE 07 common cold (AE no. 07)	100 mg 3x/d	12Jun2017	15Jun2017		AE-7
		20AUG2015	18NOV2015	LENDORM	BROTIZOLAM	PSYCHOLEPTICS	Other: INSOMNIA PROPHYLACTIC	0.25 mg	20Aug2015	20Aug2015		
		20AUG2015	18NOV2015	MEXA-VIT-C (PARACETAMOL + VITAMIN C)	BIOGESIC /00411801/	ANALGESICS	Other: COMMON COLD (AE no. 01)	500 mg	22Oct2015	23Oct2015		AE-1
		20AUG2015	18NOV2015	TUSSAMAG (THYMUS VULGARIS L)	THYMUS VULGARIS FLUID EXTRACT	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	Other: COLD (AE no. 01)	3 x 10 ml	13Nov2015	15Nov2015		AE-1
		20AUG2015	18NOV2015	Ospexin (Cefalexin)	CEFALEXIN	ANTIBACTERIALS FOR SYSTEMIC USE	Pain-other (AE no. 06)	1000 mg 1-1-1	21Apr2017	24Apr2017		AE-6
		20AUG2015	18NOV2015	Ospen	PHENOXYMETHYLPE NICILLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: AE 06 tooth pain (AE no. 06)	1000 mg 3x/d	16Nov2017	19Nov2017		AE-6
		20AUG2015	18NOV2015	DOMINAL (PROTHIPENDYL HYDROCHLORID MONOHYDRAT)	PROTHIPENDYL HYDROCHLORIDE	PSYCHOLEPTICS	Other: INSOMNIA PROPHYLACTIC	7.5 mg	22Aug2015	22Aug2015		
		20AUG2015	18NOV2015	MEXA-VIT-C (PARACETAMOL + VITAMIN C)	BIOGESIC /00411801/	ANALGESICS	Other: COMMON COLD (AE no. 01)	500 mg	02Nov2015	04Nov2015		AE-1
		20AUG2015	18NOV2015	BRONCHO STOP (ALTHRA OFFICINALIS L, THYMUS VULGARIS L, ASCORBIC ACID)	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE (90116001001)	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	Other: COLD (AE no. 02)	45 ml	23Nov2015	26Nov2015		AE-2
		20AUG2015	18NOV2015	Mucosolvan (Ambroxol)	AMBROXOL HYDROCHLORIDE	COUGH AND COLD PREPARATIONS	Other: Bronchitis (AE no. 07)	100 ml 1-1-1	12Jun2017	15Jun2017		AE-7

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0147	ND plus	20AUG2015	18NOV2015	Mucosolvan (Ambroxol)	AMBROXOL HYDROCHLORIDE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: Bronchitis (AE no. 07)	100 ml 1-1-1	12Jun2017	15Jun2017		AE-7
		20AUG2015	18NOV2015	Mucosolvan (Ambroxol)	AMBROXOL HYDROCHLORIDE	THROAT PREPARATIONS	Other: Bronchitis (AE no. 07)	100 ml 1-1-1	12Jun2017	15Jun2017		AE-7
		20AUG2015	18NOV2015	Seractil 400 mg	DEXIBUPROFEN	ANTIINFLAMMATO RY AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 06)	if needed	16Nov2017	18Nov2017		AE-6
		20AUG2015	18NOV2015	Seractil 400 mg	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 06)	if needed	16Nov2017	18Nov2017		AE-6
01/0148	ND plus	22OCT2015	12JAN2016	Symbicort	BUDESONIDE W/FORMOTEROL FUMARATE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: Asthma (MedHis no. 01)	1x	2000		Yes	MH-1
		22OCT2015	12JAN2016	LENDORM	BROTIZOLAM	PSYCHOLEPTICS	Other: SLEEPING INDUCTION PROPHYLACTIC	0.25 mg	21Oct2015	25Oct2015		
		22OCT2015	12JAN2016	ACICLOVIR (for 1 week)	ACICLOVIR	OPHTHALMOLOGICA LS	Other: HERPES ZOSTER (AE no. 04)	800 mg per dose	May2017	May2017		AE-4
		22OCT2015	12JAN2016	ACICLOVIR (for 1 week)	ACICLOVIR	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: HERPES ZOSTER (AE no. 04)	800 mg per dose	May2017	May2017		AE-4
		22OCT2015	12JAN2016	ACICLOVIR (for 1 week)	ACICLOVIR	ANTIVIRALS FOR SYSTEMIC USE	Other: HERPES ZOSTER (AE no. 04)	800 mg per dose	May2017	May2017		AE-4
		22OCT2015	12JAN2016	Sirdalud	TIZANIDINE HYDROCHLORIDE	MUSCLE RELAXANTS	Pain-other (AE no. 05)	2 mg	13Feb2019	Mar2019		AE-5
		22OCT2015	12JAN2016	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Ulcera Prophylaxis	20 mg	21Oct2015	02Nov2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0148	ND plus	22OCT2015	12JAN2016	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	21Oct2015	24Oct2015		
		22OCT2015	12JAN2016	Amoxicillin	AMOXICILLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: H.P. Eradication (AE no. 02)	2000 mg	27Jan2016	09Feb2016		AE-2
		22OCT2015	12JAN2016	LOTIO ALBA (Zinc) ointment	ZINC OXIDE	MEDICATED DRESSINGS	Other: HERPES ZOSTER (AE no. 04)	as needed	May2017	May2017		AE-4
		22OCT2015	12JAN2016	LOTIO ALBA (Zinc) ointment	ZINC OXIDE	EMOLLIENTS AND PROTECTIVES	Other: HERPES ZOSTER (AE no. 04)	as needed	May2017	May2017		AE-4
		22OCT2015	12JAN2016	Neocitran (Ascorbic acid, Paracetamol, Pheniramin-Maleat , Phenylephrin-Hydr ochlorid)	NEO CITRAN /00438101/	ANALGESICS	Other: Common cold (AE no. 07)	500 mg	Jan2019	Jan2019		AE-7
		22OCT2015	12JAN2016	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	22Oct2015	22Oct2015		
		22OCT2015	12JAN2016	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	22Oct2015	22Oct2015		
		22OCT2015	12JAN2016	Metronidazol	METRONIDAZOLE	ANTIBACTERIALS FOR SYSTEMIC USE	Other: H.P. Eradication (AE no. 02)	800 mg	27Jan2016	09Feb2016		AE-2
		22OCT2015	12JAN2016	Metronidazol	METRONIDAZOLE	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: H.P. Eradication (AE no. 02)	800 mg	27Jan2016	09Feb2016		AE-2
		22OCT2015	12JAN2016	Metronidazol	METRONIDAZOLE	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: H.P. Eradication (AE no. 02)	800 mg	27Jan2016	09Feb2016		AE-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0148	ND plus	22OCT2015	12JAN2016	Metronidazol	METRONIDAZOLE	STOMATOLOGICAL PREPARATIONS	Other: H.P. Eradication (AE no. 02)	800 mg	27Jan2016	09Feb2016		AE-2
		22OCT2015	12JAN2016	Metronidazol	METRONIDAZOLE	ANTIPROTOZOALS	Other: H.P. Eradication (AE no. 02)	800 mg	27Jan2016	09Feb2016		AE-2
		22OCT2015	12JAN2016	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	12Jan2016	13Jan2016		
		22OCT2015	12JAN2016	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: H.P. Eradication (AE no. 02)	40 mg	27Jan2016	09Feb2016		AE-2
01/0149	ND plus	03DEC2015	01MAR2016	Pantoloc	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Ulcera Prophylaxis	40 mg	01Dec2015	09Dec2015		
		03DEC2015	01MAR2016	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	03Dec2015	03Dec2015		
		03DEC2015	01MAR2016	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	03Dec2015	03Dec2015		
		03DEC2015	01MAR2016	Clavamox	SPEKTRAMOX	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Urinary tract infection (AE no. 03)	1 g	Jan2017	Feb2017		AE-3
		03DEC2015	01MAR2016	Tantum verde (Benzylamin)	BENZYLAMINE HYDROCHLORIDE	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: Bronchitis (AE no. 05)	3 mg x 3	Feb2018	02Mar2018		AE-5
		03DEC2015	01MAR2016	Tantum verde (Benzylamin)	BENZYLAMINE HYDROCHLORIDE	OTHER GYNECOLOGICALS	Other: Bronchitis (AE no. 05)	3 mg x 3	Feb2018	02Mar2018		AE-5
		03DEC2015	01MAR2016	Tantum verde (Benzylamin)	BENZYLAMINE HYDROCHLORIDE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: Bronchitis (AE no. 05)	3 mg x 3	Feb2018	02Mar2018		AE-5

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing? MH/AE	Assoc iated with MH/AE
01/0149	ND plus	03DEC2015	01MAR2016	Tantum verde (Benzylamin)	BENZYLAMINE HYDROCHLORIDE	THROAT PREPARATIONS	Other: Bronchitis (AE no. 05)	3 mg x 3	Feb2018	02Mar2018		AE-5
		03DEC2015	01MAR2016	Tantum verde (Benzylamin)	BENZYLAMINE HYDROCHLORIDE	STOMATOLOGICAL PREPARATIONS	Other: Bronchitis (AE no. 05)	3 mg x 3	Feb2018	02Mar2018		AE-5
		03DEC2015	01MAR2016	antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: urinary tract inf. (AE no. 09)	UNK	Nov2020	Nov2020		AE-9
		03DEC2015	01MAR2016	antibiotics (name unknown)	ANTIBIOTICS (90046601001)	VASOPROTECTIVES	Other: urinary tract inf. (AE no. 09)	UNK	Nov2020	Nov2020		AE-9
		03DEC2015	01MAR2016	antibiotics (name unknown)	ANTIBIOTICS (90046601001)	THROAT PREPARATIONS	Other: urinary tract inf. (AE no. 09)	UNK	Nov2020	Nov2020		AE-9
		03DEC2015	01MAR2016	antibiotics (name unknown)	ANTIBIOTICS (90046601001)	OPHTHALMOLOGICA LS	Other: urinary tract inf. (AE no. 09)	UNK	Nov2020	Nov2020		AE-9
		03DEC2015	01MAR2016	antibiotics (name unknown)	ANTIBIOTICS (90046601001)	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: urinary tract inf. (AE no. 09)	UNK	Nov2020	Nov2020		AE-9
		03DEC2015	01MAR2016	antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: urinary tract inf. (AE no. 09)	UNK	Nov2020	Nov2020		AE-9
		03DEC2015	01MAR2016	antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIFUNGALS FOR DERMATOLOGICAL USE	Other: urinary tract inf. (AE no. 09)	UNK	Nov2020	Nov2020		AE-9
		03DEC2015	01MAR2016	antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIMYCOBACTERI ALS	Other: urinary tract inf. (AE no. 09)	UNK	Nov2020	Nov2020		AE-9
		03DEC2015	01MAR2016	antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIBACTERIALS FOR SYSTEMIC USE	Other: urinary tract inf. (AE no. 09)	UNK	Nov2020	Nov2020		AE-9

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0149	ND plus	03DEC2015	01MAR2016	antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIMYCOTICS FOR SYSTEMIC USE	Other: urinary tract inf. (AE no. 09)	UNK	Nov2020	Nov2020		AE-9
		03DEC2015	01MAR2016	OTRIVIN	XYLOMETAZOLINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Other: COLD (AE no. 01)	2 x day	07Jan2016	15Jan2016		AE-1
		03DEC2015	01MAR2016	OTRIVIN	XYLOMETAZOLINE HYDROCHLORIDE	NASAL PREPARATIONS	Other: COLD (AE no. 01)	2 x day	07Jan2016	15Jan2016		AE-1
		03DEC2015	01MAR2016	Schuessler salts	HOMEOPATHIC PREPARATION (90113701001)	HOMEOPATHIC PREPARATION	Other: urinary tract inf. (AE no. 09)	UNK	Nov2020	Nov2020		AE-9
		03DEC2015	01MAR2016	Schuessler salts	HOMEOPATHIC PREPARATION (90113701001)	ALL OTHER THERAPEUTIC PRODUCTS	Other: urinary tract inf. (AE no. 09)	UNK	Nov2020	Nov2020		AE-9
		03DEC2015	01MAR2016	Lendorm	BROTIZOLAM	PSYCHOLEPTICS	Other: Sleep Induction Prophylactic	0.25 mg	06Dec2015	06Dec2015		
		03DEC2015	01MAR2016	OTRIVIN	XYLOMETAZOLINE HYDROCHLORIDE	NASAL PREPARATIONS	Other: COLD (AE no. 02)	2 x day	28Jan2016	02Feb2016		AE-2
		03DEC2015	01MAR2016	OTRIVIN	XYLOMETAZOLINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Other: COLD (AE no. 02)	2 x day	28Jan2016	02Feb2016		AE-2
		03DEC2015	01MAR2016	Lovenox	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombosis Prophylaxis	40 mg	01Dec2015	06Dec2015		
01/0150		03FEB2016	-	CARVEDILOL	CARVEDILOL	BETA BLOCKING AGENTS	Other: HYPERTENSION (MedHis no. 01)	12.5 mg	2013		Yes	MH-1
01/0151	ND basic	03MAR2016	07JUN2016	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE NEO CITRAN	DRUGS FOR ACID RELATED DISORDERS ANALGESICS	Other: ULCERA PROPHYLAXIS	40 mg	18Jan2016	06Mar2016		
		03MAR2016	07JUN2016	Neocitran (Paracetamol, Ascorbic acid, Pheniramin-Maleat , Phenylephrin-Hydr ochlorid)	/00438101/		Other: Common Cold (AE no. 01)	3 x 1 p	2018	2018		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing? MH/AE	Assoc iated with MH/AE
01/0151	ND basic	03MAR2016	07JUN2016	antibiotics (name/dose unknown)	ANTIBIOTICS (90046601001)	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR therapy (AE Y/ANTIINFECTIVE no. 03) AGENTS	Other: Infection therapy (AE no. 03)	unknown	Jan2020	Jan2020		AE-3
		03MAR2016	07JUN2016	antibiotics (name/dose unknown)	ANTIBIOTICS (90046601001)	VASOPROTECTIVES	Other: Infection therapy (AE no. 03)	unknown	Jan2020	Jan2020		AE-3
		03MAR2016	07JUN2016	antibiotics (name/dose unknown)	ANTIBIOTICS (90046601001)	THROAT PREPARATIONS	Other: Infection therapy (AE no. 03)	unknown	Jan2020	Jan2020		AE-3
		03MAR2016	07JUN2016	antibiotics (name/dose unknown)	ANTIBIOTICS (90046601001)	OPHTHALMOLOGICA LS	Other: Infection therapy (AE no. 03)	unknown	Jan2020	Jan2020		AE-3
		03MAR2016	07JUN2016	antibiotics (name/dose unknown)	ANTIBIOTICS (90046601001)	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Infection therapy (AE no. 03)	unknown	Jan2020	Jan2020		AE-3
		03MAR2016	07JUN2016	antibiotics (name/dose unknown)	ANTIBIOTICS (90046601001)	ANTIMYCOBACTERI ALS	Other: Infection therapy (AE no. 03)	unknown	Jan2020	Jan2020		AE-3
		03MAR2016	07JUN2016	antibiotics (name/dose unknown)	ANTIBIOTICS (90046601001)	ANTIMYCOTICS FOR SYSTEMIC USE	Other: Infection therapy (AE no. 03)	unknown	Jan2020	Jan2020		AE-3
		03MAR2016	07JUN2016	antibiotics (name/dose unknown)	ANTIBIOTICS (90046601001)	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: Infection therapy (AE no. 03)	unknown	Jan2020	Jan2020		AE-3
		03MAR2016	07JUN2016	antibiotics (name/dose unknown)	ANTIBIOTICS (90046601001)	ANTIFUNGALS FOR DERMATOLOGICAL USE	Other: Infection therapy (AE no. 03)	unknown	Jan2020	Jan2020		AE-3

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing? with MH/AE	Assoc iated
01/0151	ND basic	03MAR2016	07JUN2016	antibiotics (name/dose unknown)	ANTIBIOTICS (90046601001)	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: Infection therapy (AE no. 03)	unknown	Jan2020	Jan2020		AE-3
		03MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: bacterial infection (AE no. 05)	UNK	Jan2021	Jan2021		AE-5
		03MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIFUNGALS FOR DERMATOLOGICAL USE	Other: bacterial infection (AE no. 05)	UNK	Jan2021	Jan2021		AE-5
		03MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: bacterial infection (AE no. 05)	UNK	Jan2021	Jan2021		AE-5
		03MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIMYCOBACTERI ALS	Other: bacterial infection (AE no. 05)	UNK	Jan2021	Jan2021		AE-5
		03MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIMYCOTICS FOR SYSTEMIC USE	Other: bacterial infection (AE no. 05)	UNK	Jan2021	Jan2021		AE-5
		03MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIBACTERIALS FOR SYSTEMIC USE	Other: bacterial infection (AE no. 05)	UNK	Jan2021	Jan2021		AE-5
		03MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	OPHTHALMOLOGICA LS	Other: bacterial infection (AE no. 05)	UNK	Jan2021	Jan2021		AE-5

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing? MH/AE	Assoc iated with MH/AE
01/0151	ND basic	03MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	THROAT PREPARATIONS	Other: bacterial infection (AE no. 05)	UNK	Jan2021	Jan2021		AE-5
		03MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	VASOPROTECTIVES	Other: bacterial infection (AE no. 05)	UNK	Jan2021	Jan2021		AE-5
		03MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: bacterial infection (AE no. 05)	UNK	Jan2021	Jan2021		AE-5
		03MAR2016	07JUN2016	Acetylcystein	ACETYLCYSTEINE	COUGH AND COLD PREPARATIONS	Other: Common Cold (AE no. 01)	3 x 200 mg	2018	2018		AE-1
		03MAR2016	07JUN2016	Acetylcystein	ACETYLCYSTEINE	OPHTHALMOLOGICA LS	Other: Common Cold (AE no. 01)	3 x 200 mg	2018	2018		AE-1
		03MAR2016	07JUN2016	Acetylcystein	ACETYLCYSTEINE	NASAL PREPARATIONS	Other: Common Cold (AE no. 01)	3 x 200 mg	2018	2018		AE-1
		03MAR2016	07JUN2016	Acetylcystein	ACETYLCYSTEINE	OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	Other: Common Cold (AE no. 01)	3 x 200 mg	2018	2018		AE-1
		03MAR2016	07JUN2016	Acetylcystein	ACETYLCYSTEINE	ALL OTHER THERAPEUTIC PRODUCTS	Other: Common Cold (AE no. 01)	3 x 200 mg	2018	2018		AE-1
		03MAR2016	07JUN2016	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	04Mar2016	06Mar2016		
		03MAR2016	07JUN2016	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	03Mar2016	03Mar2016		
		03MAR2016	07JUN2016	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	03Mar2016	03Mar2016		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0152	SC	03MAR2016	-	ACTIVEVLE	KLIOGEST	SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	Other: HORMONE SUBSTITUTION	1 mg/0.5 mg	UNK		Yes	
		03MAR2016	-	BUSCOPAN	HYOSCINE BUTYLBROMIDE	DRUGS FOR FUNCTIONAL GASTROINTESTINA L DISORDERS	Other: PONV (AE no. 01 02 03)	10 mg	03Mar2016	03Mar2016		
		03MAR2016	-	Seractil fte	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 04)	400 mg if needed	Apr2018		Yes	AE-4
		03MAR2016	-	Seractil fte	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 04)	400 mg if needed	Apr2018		Yes	AE-4
		03MAR2016	-	Penicillin	BETA-LACTAM ANTIBACTERIALS, PENICILLINS (90028401001)	ANTIBACTERIALS FOR SYSTEMIC USE	Other: AE06 (AE no. 06)	UNK	Dec2020	Dec2020		AE-6
		03MAR2016	-	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg if needed	Nov2015	14Mar2016		
		03MAR2016	-	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	02Mar2016	06Mar2016		
		03MAR2016	-	Diclovit (Diclofenac)	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 05)	100 mg	23Jan2020	31Jan2020		AE-5
		03MAR2016	-	Diclovit (Diclofenac)	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 05)	100 mg	23Jan2020	31Jan2020		AE-5
		03MAR2016	-	Diclovit (Diclofenac)	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 05)	100 mg	23Jan2020	31Jan2020		AE-5
		03MAR2016	-	Diclovit (Diclofenac)	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain-other (AE no. 05)	100 mg	23Jan2020	31Jan2020		AE-5

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0152	SC	03MAR2016	-	Diclovit (Diclofenac)	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain-other (AE no. 05)	100 mg	23Jan2020	31Jan2020		AE-5
		03MAR2016	-	Diclovit (Diclofenac)	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 05)	100 mg	23Jan2020	31Jan2020		AE-5
		03MAR2016	-	CEFUXOXIM	CEFUXOXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	03Mar2016	03Mar2016		
		03MAR2016	-	CEFUXOXIM	CEFUXOXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	03Mar2016	03Mar2016		
		03MAR2016	-	KYTRIL	GRANISETRON HYDROCHLORIDE	ANTIEMETICS AND	Other: PONV (AE no. 01 02 03)	3 mg	03Mar2016	03Mar2016		
		03MAR2016	-	LENDORM	BROTIZOLAM	PSYCHOLEPTICS	Other: SLEEPING INDUCTION PROPHYLACTIC	0.25 mg	02Mar2016	05Mar2016		
01/0153	ND basic	21MAR2016	07JUN2016	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 01)	1200 mg	15Jun2016	Jan2017		AE-1
		21MAR2016	07JUN2016	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 01)	1200 mg	15Jun2016	Jan2017		AE-1
		21MAR2016	07JUN2016	NEODOLPASSE DICLOFENAC 75 mg ORPHENADRIN HYDROGEN-CITRAT 30 mg	NEODOLPASSE	MUSCLE RELAXANTS	Pain-other (AE no. 01)	250 ml 75/30 mg	25Jun2016	01Jul2016		AE-1
		21MAR2016	07JUN2016	Solu Celestan	BETAMETHASONE SODIUM PHOSPHATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 01)	1 ml	07Jun2017	07Jun2017		AE-1
		21MAR2016	07JUN2016	Solu Celestan	BETAMETHASONE SODIUM PHOSPHATE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 01)	1 ml	07Jun2017	07Jun2017		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0153	ND basic	21MAR2016	07JUN2016	Solu Celestan	BETAMETHASONE SODIUM PHOSPHATE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-other (AE no. 01)	1 ml	07Jun2017	07Jun2017		AE-1
		21MAR2016	07JUN2016	Solu Celestan	BETAMETHASONE SODIUM PHOSPHATE	OPHTHALMOLOGICA LS	Pain-other (AE no. 01)	1 ml	07Jun2017	07Jun2017		AE-1
		21MAR2016	07JUN2016	Solu Celestan	BETAMETHASONE SODIUM PHOSPHATE	NASAL PREPARATIONS	Pain-other (AE no. 01)	1 ml	07Jun2017	07Jun2017		AE-1
		21MAR2016	07JUN2016	Solu Celestan	BETAMETHASONE SODIUM PHOSPHATE	VASOPROTECTIVES	Pain-other (AE no. 01)	1 ml	07Jun2017	07Jun2017		AE-1
		21MAR2016	07JUN2016	Solu Celestan	BETAMETHASONE SODIUM PHOSPHATE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Pain-other (AE no. 01)	1 ml	07Jun2017	07Jun2017		AE-1
		21MAR2016	07JUN2016	Solu Celestan	BETAMETHASONE SODIUM PHOSPHATE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Pain-other (AE no. 01)	1 ml	07Jun2017	07Jun2017		AE-1
		21MAR2016	07JUN2016	Solu Celestan	BETAMETHASONE SODIUM PHOSPHATE	OTOLOGICALS	Pain-other (AE no. 01)	1 ml	07Jun2017	07Jun2017		AE-1
		21MAR2016	07JUN2016	Tresiba (Insulin Degludec)	INSULIN DEGLUDEC	DRUGS USED IN DIABETES	Other: DMI (AE no. 02)	UNK	26Jan2018	31Jan2018		AE-2
		21MAR2016	07JUN2016	PARKEMED	MEFENAMIC ACID	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 05)	500 mg if needed	Nov2018	Feb2019		AE-5
		21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: bacterial infection (AE no. 10)	unknown	Jan2020	Jan2020		AE-10

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0153	ND basic	21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: bacterial infection (AE no. 10)	unknown	Jan2020	Jan2020	AE-10
		21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIFUNGALS FOR DERMATOLOGICAL USE	Other: bacterial infection (AE no. 10)	unknown	Jan2020	Jan2020	AE-10
		21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIMYCOBACTERI ALS	Other: bacterial infection (AE no. 10)	unknown	Jan2020	Jan2020	AE-10
		21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIMYCOTICS FOR SYSTEMIC USE	Other: bacterial infection (AE no. 10)	unknown	Jan2020	Jan2020	AE-10
		21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIBACTERIALS FOR SYSTEMIC USE	Other: bacterial infection (AE no. 10)	unknown	Jan2020	Jan2020	AE-10
		21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	THROAT PREPARATIONS	Other: bacterial infection (AE no. 10)	unknown	Jan2020	Jan2020	AE-10
		21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	OPHTHALMOLOGICA LS	Other: bacterial infection (AE no. 10)	unknown	Jan2020	Jan2020	AE-10
		21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	VASOPROTECTIVES	Other: bacterial infection (AE no. 10)	unknown	Jan2020	Jan2020	AE-10
		21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: bacterial infection (AE no. 10)	unknown	Jan2020	Jan2020	AE-10

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0153	ND basic	21MAR2016	07JUN2016	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ULCERA PROPHYLAXIS	40 mg	08Mar2016	28Mar2016		
		21MAR2016	07JUN2016	LOVENOX	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: THROMBOSIS PROPHYLAXIS	40 mg	22Mar2016	24Mar2016		
		21MAR2016	07JUN2016	NEODOLPASSE DICLOFENAC 75 mg ORPHENADRIN HYDROGEN-CITRAT 30 mg	NEODOLPASSE	MUSCLE RELAXANTS	Pain-other (AE no. 01)	250 ml 75/30 mg	11Jul2016	19Jul2016		AE-1
		21MAR2016	07JUN2016	Bucain	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain-other (AE no. 01)	1 ml	07Jun2017	07Jun2017		AE-1
		21MAR2016	07JUN2016	Bucain	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain-other (AE no. 01)	1 ml	07Jun2017	07Jun2017		AE-1
		21MAR2016	07JUN2016	Novarapid (Insulin aspart)	INSULIN ASPART	DRUGS USED IN DIABETES	Other: DMI (AE no. 02)	UNK	26Jan2018	31Jan2018		AE-2
		21MAR2016	07JUN2016	SERACTIL FORTE	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 05)	400 mg if needed	Nov2018	Feb2019		AE-5
		21MAR2016	07JUN2016	SERACTIL FORTE	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 05)	400 mg if needed	Nov2018	Feb2019		AE-5
		21MAR2016	07JUN2016	Thomapyrin (250 mg ASS, 200 mg Paracetamole, 50 mg Coffeine)	THOMAPYRIN N	ANALGESICS	Pain-other (AE no. 07)	1x/month (if migraine attack)	May2019		Yes	AE-7
		21MAR2016	07JUN2016	CEFUROXIM	CEFUROXIME	OPHTHALMOLOGICA LS	Other: INFECTION PROPHYLAXIS	1500 mg	21Mar2016	21Mar2016		
		21MAR2016	07JUN2016	CEFUROXIM	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: INFECTION PROPHYLAXIS	1500 mg	21Mar2016	21Mar2016		
		21MAR2016	07JUN2016	Tresiba (Insulin Degludec)	INSULIN DEGLUDEC	DRUGS USED IN DIABETES	Other: DMI (AE no. 03)	UNK	01Feb2018		Yes	AE-3

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0153	ND basic	21MAR2016	07JUN2016	PANTOLOC	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ulcer prophylaxis (AE no. 05)	40 mg	Nov2018	Feb2019		AE-5
		21MAR2016	07JUN2016	Toujeo	INSULIN GLARGINE	DRUGS USED IN DIABETES	Other: DMI (AE no. 02)	UNK	Jul2020		Yes	AE-2
		21MAR2016	07JUN2016	Novarapid (Insulin aspart)	INSULIN ASPART	DRUGS USED IN DIABETES	Other: DMI (AE no. 03)	UNK	01Feb2018		Yes	AE-3
		21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: bacterial infection (AE no. 08)	unknown	Oct2019	Oct2019		AE-8
		21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	VASOPROTECTIVES	Other: bacterial infection (AE no. 08)	unknown	Oct2019	Oct2019		AE-8
		21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	OPHTHALMOLOGICA LS	Other: bacterial infection (AE no. 08)	unknown	Oct2019	Oct2019		AE-8
		21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	THROAT PREPARATIONS	Other: bacterial infection (AE no. 08)	unknown	Oct2019	Oct2019		AE-8
		21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIMYCOBACTERI ALS	Other: bacterial infection (AE no. 08)	unknown	Oct2019	Oct2019		AE-8
		21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIMYCOTICS FOR SYSTEMIC USE	Other: bacterial infection (AE no. 08)	unknown	Oct2019	Oct2019		AE-8
		21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIBACTERIALS FOR SYSTEMIC USE	Other: bacterial infection (AE no. 08)	unknown	Oct2019	Oct2019		AE-8

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing? MH/AE	Assoc iated with MH/AE
01/0153	ND basic	21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: bacterial infection (AE no. 08)	unknown	Oct2019	Oct2019		AE-8
		21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: bacterial infection (AE no. 08)	unknown	Oct2019	Oct2019		AE-8
		21MAR2016	07JUN2016	Antibiotics (name unknown)	ANTIBIOTICS (90046601001)	ANTIFUNGALS FOR DERMATOLOGICAL USE	Other: bacterial infection (AE no. 08)	unknown	Oct2019	Oct2019		AE-8
		21MAR2016	07JUN2016	Voltaren 75 mg/3 ml	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 11)	75 mg / 3 ml 1-2 / month	Jul2020	May2021		AE-11
		21MAR2016	07JUN2016	Voltaren 75 mg/3 ml	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain-other (AE no. 11)	75 mg / 3 ml 1-2 / month	Jul2020	May2021		AE-11
		21MAR2016	07JUN2016	Voltaren 75 mg/3 ml	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain-other (AE no. 11)	75 mg / 3 ml 1-2 / month	Jul2020	May2021		AE-11
		21MAR2016	07JUN2016	Voltaren 75 mg/3 ml	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 11)	75 mg / 3 ml 1-2 / month	Jul2020	May2021		AE-11
		21MAR2016	07JUN2016	Voltaren 75 mg/3 ml	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 11)	75 mg / 3 ml 1-2 / month	Jul2020	May2021		AE-11
		21MAR2016	07JUN2016	Voltaren 75 mg/3 ml	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 11)	75 mg / 3 ml 1-2 / month	Jul2020	May2021		AE-11
02/0201	ND plus	13FEB2013	07MAY2013	Ibuprofen 600	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1x600mg/day	12Jan2013	12Feb2013		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0201	ND plus	13FEB2013	07MAY2013	Ibuprofen 600	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1x600mg/day	12Jan2013	12Feb2013	
		13FEB2013	07MAY2013	Ibuprofen 600	IBUPROFEN	OTHER GYNECOLOGICALS	Pain	1x600mg/day	12Jan2013	12Feb2013	
		13FEB2013	07MAY2013	Ibuprofen 600	IBUPROFEN	THROAT PREPARATIONS	Pain	1x600mg/day	12Jan2013	12Feb2013	
		13FEB2013	07MAY2013	Ibuprofen 600	IBUPROFEN	CARDIAC THERAPY	Pain	1x600mg/day	12Jan2013	12Feb2013	
		13FEB2013	07MAY2013	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	postoperative pain	3 x 1500 mg	28Dec2015	28Mar2016	
		13FEB2013	07MAY2013	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Antibiosis	1500 mg	29Dec2015	29Dec2015	
		13FEB2013	07MAY2013	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: Antibiosis	1500 mg	29Dec2015	29Dec2015	
		13FEB2013	07MAY2013	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	stomach protection	40 mg	28Dec2015	28Mar2016	
		13FEB2013	07MAY2013	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Stomach Protection	40 mg	12Feb2013	20Feb2013	
		13FEB2013	07MAY2013	Clexane s.c.	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	thrombosis prevention	40 mg	28Dec2015	03Jan2016	
		13FEB2013	07MAY2013	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombosis prevention	40 mg	12Feb2013	19Feb2013	
		13FEB2013	07MAY2013	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	postoperative pain	3 x 600 mg	28Dec2015	28Mar2016	
		13FEB2013	07MAY2013	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	postoperative pain	3 x 600 mg	28Dec2015	28Mar2016	
		13FEB2013	07MAY2013	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	postoperative pain	3 x 600 mg	28Dec2015	28Mar2016	
		13FEB2013	07MAY2013	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	postoperative pain	3 x 600 mg	28Dec2015	28Mar2016	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0201	ND plus	13FEB2013	07MAY2013	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	postoperative pain	3 x 600 mg	28Dec2015	28Mar2016	
		13FEB2013	07MAY2013	Forte cortin 4 mg	DEXAMETHASONE	VASOPROTECTIVES	Swelling prevention, anti inflammatory	12 mg	14Feb2013	16Feb2013	
		13FEB2013	07MAY2013	Forte cortin 4 mg	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Swelling prevention, anti inflammatory	12 mg	14Feb2013	16Feb2013	
		13FEB2013	07MAY2013	Forte cortin 4 mg	DEXAMETHASONE	OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	Swelling prevention, anti inflammatory	12 mg	14Feb2013	16Feb2013	
		13FEB2013	07MAY2013	Forte cortin 4 mg	DEXAMETHASONE	OTOLOGICALS	Swelling prevention, anti inflammatory	12 mg	14Feb2013	16Feb2013	
		13FEB2013	07MAY2013	Forte cortin 4 mg	DEXAMETHASONE	NASAL PREPARATIONS	Swelling prevention, anti inflammatory	12 mg	14Feb2013	16Feb2013	
		13FEB2013	07MAY2013	Forte cortin 4 mg	DEXAMETHASONE	OPHTHALMOLOGICALS	Swelling prevention, anti inflammatory	12 mg	14Feb2013	16Feb2013	
		13FEB2013	07MAY2013	Forte cortin 4 mg	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Swelling prevention, anti inflammatory	12 mg	14Feb2013	16Feb2013	
		13FEB2013	07MAY2013	Forte cortin 4 mg	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Swelling prevention, anti inflammatory	12 mg	14Feb2013	16Feb2013	
		13FEB2013	07MAY2013	Forte cortin 4 mg	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Swelling prevention, anti inflammatory	12 mg	14Feb2013	16Feb2013	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0201	ND plus	13FEB2013	07MAY2013	Forte cortin 4 mg	DEXAMETHASONE	CORTICOSTEROIDS	Swelling prevention, anti-inflammatory	12 mg	14Feb2013	16Feb2013	
		13FEB2013	07MAY2013	Forte cortin 4 mg	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Swelling prevention, anti-inflammatory	12 mg	14Feb2013	16Feb2013	
		13FEB2013	07MAY2013	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Antebiose	1500 mg	13Feb2013	13Feb2013	
		13FEB2013	07MAY2013	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICALS	Antebiose	1500 mg	13Feb2013	13Feb2013	
02/0202	ND basic	20MAR2013	-	Lactuflor Sirup	LACTULOSE	BILE AND LIVER THERAPY	Prophylaxis	1 x 10 ml	18Mar2013	Apr2013	
		20MAR2013	-	Lactuflor Sirup	LACTULOSE	DRUGS FOR CONSTIPATION	Prophylaxis	1 x 10 ml	18Mar2013	Apr2013	
		20MAR2013	-	Arixtra 7.5 mg	FONDAPARINUX SODIUM	ANTITHROMBOTIC AGENTS	Thrombosis Prophylaxis	1 x 1 7.5 mg	14Mar2013	UNK	
		20MAR2013	-	Pantoprazol 40 (as Natrium)	PANTOPRAZOLE SODIUM	DRUGS FOR ACID RELATED DISORDERS	Stomach Prophylaxis	1 x 1 40 mg	14Mar2013	Apr2013	
		20MAR2013	-	Cefuroxin	CEFUROXIME SODIUM	OPHTHALMOLOGICALS	Antibiose infection prophylaxis	1 x 1 500 mg	20Mar2013	20Mar2013	
		20MAR2013	-	Cefuroxin	CEFUROXIME SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Antibiose infection prophylaxis	1 x 1 500 mg	20Mar2013	20Mar2013	
02/0203	ND basic	28MAR2013	26JUN2013	Pantoprazol	PANTOPRAZOLE SODIUM	DRUGS FOR ACID RELATED DISORDERS	Stomach protector	40 mg	27Mar2013	03Apr2013	
		28MAR2013	26JUN2013	Xylocain 2%	SESQUIHYDRATE LIDOCAINE	THROAT PREPARATIONS	local anaesthesia (infiltration)	5 ml	26Feb2014	26Feb2014	
		28MAR2013	26JUN2013	Xylocain 2%	LIDOCAINE	OPHTHALMOLOGICALS	local anaesthesia (infiltration)	5 ml	26Feb2014	26Feb2014	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0203	ND basic	28MAR2013	26JUN2013	Xylocain 2%	LIDOCAINE	VASOPROTECTIVES	local anaesthesia (infiltration)	5 ml	26Feb2014	26Feb2014	
		28MAR2013	26JUN2013	Xylocain 2%	LIDOCAINE	CARDIAC THERAPY	local anaesthesia (infiltration)	5 ml	26Feb2014	26Feb2014	
		28MAR2013	26JUN2013	Xylocain 2%	LIDOCAINE	STOMATOLOGICAL PREPARATIONS	local anaesthesia (infiltration)	5 ml	26Feb2014	26Feb2014	
		28MAR2013	26JUN2013	Xylocain 2%	LIDOCAINE	OTOLOGICALS	local anaesthesia (infiltration)	5 ml	26Feb2014	26Feb2014	
		28MAR2013	26JUN2013	Xylocain 2%	LIDOCAINE	UROLOGICALS	local anaesthesia (infiltration)	5 ml	26Feb2014	26Feb2014	
		28MAR2013	26JUN2013	Xylocain 2%	LIDOCAINE	ANTIPRURITICS, INCL. ANTI HISTAMINES, ANESTHETICS, ETC.	local anaesthesia (infiltration)	5 ml	26Feb2014	26Feb2014	
		28MAR2013	26JUN2013	Xylocain 2%	LIDOCAINE	ANESTHETICS	local anaesthesia (infiltration)	5 ml	26Feb2014	26Feb2014	
		28MAR2013	26JUN2013	Volon A 40	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain - study-related	UNK	11Aug2016	11Aug2016	
		28MAR2013	26JUN2013	Volon A 40	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain - study-related	UNK	11Aug2016	11Aug2016	
		28MAR2013	26JUN2013	Volon A 40	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Pain - study-related	UNK	11Aug2016	11Aug2016	
		28MAR2013	26JUN2013	Volon A 40	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Pain - study-related	UNK	11Aug2016	11Aug2016	
		28MAR2013	26JUN2013	Volon A 40	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain - study-related	UNK	11Aug2016	11Aug2016	
		28MAR2013	26JUN2013	Volon A 40	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICALS	Pain - study-related	UNK	11Aug2016	11Aug2016	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0203	ND basic	28MAR2013	26JUN2013	Volon A 40	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Pain - study-related	UNK	11Aug2016	11Aug2016	
		28MAR2013	26JUN2013	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	anti-Xa Antithrombosis	40 mg	28Mar2013	02Apr2013	
		28MAR2013	26JUN2013	Xylocain 2%	LIDOCAINE	ANESTHETICS	local anaesthesia (infiltration)	UNK	06Mar2014	06Mar2014	
		28MAR2013	26JUN2013	Xylocain 2%	LIDOCAINE	UROLOGICALS	local anaesthesia (infiltration)	UNK	06Mar2014	06Mar2014	
		28MAR2013	26JUN2013	Xylocain 2%	LIDOCAINE	ANTIIPRURITICS, INCL. ANTIHIISTAMINES, ANESTHETICS, ETC.	local anaesthesia (infiltration)	UNK	06Mar2014	06Mar2014	
		28MAR2013	26JUN2013	Xylocain 2%	LIDOCAINE	OTOLOGICALS	local anaesthesia (infiltration)	UNK	06Mar2014	06Mar2014	
		28MAR2013	26JUN2013	Xylocain 2%	LIDOCAINE	STOMATOLOGICAL PREPARATIONS	local anaesthesia (infiltration)	UNK	06Mar2014	06Mar2014	
		28MAR2013	26JUN2013	Xylocain 2%	LIDOCAINE	CARDIAC THERAPY	local anaesthesia (infiltration)	UNK	06Mar2014	06Mar2014	
		28MAR2013	26JUN2013	Xylocain 2%	LIDOCAINE	VASOPROTECTIVES	local anaesthesia (infiltration)	UNK	06Mar2014	06Mar2014	
		28MAR2013	26JUN2013	Xylocain 2%	LIDOCAINE	OPHTHALMOLOGICA LS	local anaesthesia (infiltration)	UNK	06Mar2014	06Mar2014	
		28MAR2013	26JUN2013	Xylocain 2%	LIDOCAINE	THROAT PREPARATIONS	local anaesthesia (infiltration)	UNK	06Mar2014	06Mar2014	
		28MAR2013	26JUN2013	Xylocitin 2 %	LIDOCAINE HYDROCHLORIDE	THROAT PREPARATIONS	Pain - study-related	UNK	11Aug2016	11Aug2016	
		28MAR2013	26JUN2013	Xylocitin 2 %	LIDOCAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain - study-related	UNK	11Aug2016	11Aug2016	
		28MAR2013	26JUN2013	Xylocitin 2 %	LIDOCAINE HYDROCHLORIDE	VASOPROTECTIVES	Pain - study-related	UNK	11Aug2016	11Aug2016	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0203	ND basic	28MAR2013	26JUN2013	Xylocitin 2 %	LIDOCAINE HYDROCHLORIDE	CARDIAC THERAPY	Pain - study-related	UNK	11Aug2016	11Aug2016	
		28MAR2013	26JUN2013	Xylocitin 2 %	LIDOCAINE HYDROCHLORIDE	STOMATOLOGICAL PREPARATIONS	Pain - study-related	UNK	11Aug2016	11Aug2016	
		28MAR2013	26JUN2013	Xylocitin 2 %	LIDOCAINE HYDROCHLORIDE	OTOLOGICALS	Pain - study-related	UNK	11Aug2016	11Aug2016	
		28MAR2013	26JUN2013	Xylocitin 2 %	LIDOCAINE HYDROCHLORIDE	ANTIPRURITICS, INCL. ANTIHIISTAMINES, ANESTHETICS, ETC.	Pain - study-related	UNK	11Aug2016	11Aug2016	
		28MAR2013	26JUN2013	Xylocitin 2 %	LIDOCAINE HYDROCHLORIDE	UROLOGICALS	Pain - study-related	UNK	11Aug2016	11Aug2016	
		28MAR2013	26JUN2013	Xylocitin 2 %	LIDOCAINE HYDROCHLORIDE	ANESTHETICS	Pain - study-related	UNK	11Aug2016	11Aug2016	
		28MAR2013	26JUN2013	Volon 40	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Clucocorticoid	UNK	06Mar2014	06Mar2014	
		28MAR2013	26JUN2013	Volon 40	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICA LS	Clucocorticoid	UNK	06Mar2014	06Mar2014	
		28MAR2013	26JUN2013	Volon 40	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Clucocorticoid	UNK	06Mar2014	06Mar2014	
		28MAR2013	26JUN2013	Volon 40	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Clucocorticoid	UNK	06Mar2014	06Mar2014	
		28MAR2013	26JUN2013	Volon 40	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Clucocorticoid	UNK	06Mar2014	06Mar2014	
		28MAR2013	26JUN2013	Volon 40	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Clucocorticoid	UNK	06Mar2014	06Mar2014	
		28MAR2013	26JUN2013	Volon 40	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Clucocorticoid	UNK	06Mar2014	06Mar2014	
		28MAR2013	26JUN2013	Cefuroxin	CEFUROXIME SODIUM	OPHTHALMOLOGICA LS	Antibiose	1500 mg	28Mar2013	28Mar2013	
		28MAR2013	26JUN2013	Cefuroxin	CEFUROXIME SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Antibiose	1500 mg	28Mar2013	28Mar2013	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0203	ND basic	28MAR2013	26JUN2013	Lendomin (Brotizolam)	BROTIZOLAM	PSYCHOLEPTICS	Insomnia prophylaxis	0.25 mg	25Jun2013	28Jun2013		
02/0204	ND basic	18APR2013	-	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Antithrombosis	1 x 20 mg	20Apr2013	24Apr2013		
		18APR2013	-	Cefuroxin	CEFUROXIME SODIUM	OPHTHALMOLOGICA LS	Antibiose	1 x 1 500 mg	18Apr2013	18Apr2013		
		18APR2013	-	Cefuroxin	CEFUROXIME SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Antibiose	1 x 1 500 mg	18Apr2013	18Apr2013		
02/0205	ND basic	18APR2013	31JUL2013	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	600 mg	04Apr2013	Apr2013		
		18APR2013	31JUL2013	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain	600 mg	04Apr2013	Apr2013		
		18APR2013	31JUL2013	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	600 mg	04Apr2013	Apr2013		
		18APR2013	31JUL2013	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain	600 mg	04Apr2013	Apr2013		
		18APR2013	31JUL2013	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain	600 mg	04Apr2013	Apr2013		
		18APR2013	31JUL2013	Cefuroxin	CEFUROXIME SODIUM	OPHTHALMOLOGICA LS	Antibiose	1500 mg	18Apr2013	18Apr2013		
		18APR2013	31JUL2013	Cefuroxin	CEFUROXIME SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Antibiose	1500 mg	18Apr2013	18Apr2013		
		18APR2013	31JUL2013	Foster 100/6	BEKFORM	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: Asthma	100/6 ug	Aug2015		Yes	
		18APR2013	31JUL2013	Allopurinol 300	ALLOPURINOL	ANTIGOUT PREPARATIONS	Urea regulation	1 x 1 (300) mg	UNK		Yes	
		18APR2013	31JUL2013	Simvasbatin 60mg	SIMVASTATIN	LIPID MODIFYING AGENTS	Regulation Blood-lipide	1 x 60 mg	UNK		Yes	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0205	ND basic	18APR2013	31JUL2013	Dafiro 5/160/25	DIOVAN AML0	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Hypertension	5 mg/160 mg/25 mg	UNK		Yes	
		18APR2013	31JUL2013	Nebivolol 5	NEBIVOLOL	BETA BLOCKING AGENTS	Hypertension	1 x 5 mg	UNK		Yes	
		18APR2013	31JUL2013	Omacor	OMEGA-3-ACID ETHYL ESTER	LIPID MODIFYING AGENTS	Regulation Blood lipide	1 x 1000 mg	UNK		Yes	
		18APR2013	31JUL2013	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Phropylaxis Thrombosis	1 x 40 mg	16Apr2013	25Apr2013		
		18APR2013	31JUL2013	Pantoprazol 20 mg	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Stomach Protection	1 x 20 mg	16Apr2013	25Apr2013		
02/0206	ND plus	01JUL2013	08OCT2013	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	2400 mg	25Jun2013	20Nov2013		
		01JUL2013	08OCT2013	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain	2400 mg	25Jun2013	20Nov2013		
		01JUL2013	08OCT2013	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	2400 mg	25Jun2013	20Nov2013		
		01JUL2013	08OCT2013	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain	2400 mg	25Jun2013	20Nov2013		
		01JUL2013	08OCT2013	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain	2400 mg	25Jun2013	20Nov2013		
		01JUL2013	08OCT2013	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Antibiosis	1.5 g	01Jul2013	01Jul2013		
		01JUL2013	08OCT2013	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Antibiosis	1.5 g	01Jul2013	01Jul2013		
		01JUL2013	08OCT2013	Azathioprin	AZATHIOPRINE	IMMUNOSUPPRESSA NTS	Other: Colitis Ulcerose	150 mg	Aug2015		Yes	
		01JUL2013	08OCT2013	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain	4500 mg	25Jun2013	20Nov2013		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0206	ND plus	01JUL2013	08OCT2013	Pantoprazol	PANTOPRAZOLE	DRUGS FOR ACID	Stomach	20 mg	25Jun2013	Jul2013		
		01JUL2013	08OCT2013	Amlodipin	SESQUIHYDRATE AMLODIPINE	RELATED DISORDERS CALCIUM CHANNEL BLOCKERS	prevention (Prophylaxis) Other: Hypertension	10 mg	Aug2015		Yes	
		01JUL2013	08OCT2013	Clexane	ENOXAPARIN	ANTITHROMBOTIC	thrombosis	40 mg	01Jul2013	08Jul2013		
		01JUL2013	08OCT2013	Novalgin 500 mg/ml (Metamizol)	METAMIZOLE	AGENTS	Pain	30-120 Drops	25Jun2013	08Jul2013		
		01JUL2013	08OCT2013	Delix (Ramipril)	SODIUM RAMIPRIL	ANALGESICS	Hypertonie Hypertension	5 mg	Aug2013		Yes	
		01JUL2013	08OCT2013	Oxygesic	OXYCODONE HYDROCHLORIDE	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Pain	5 mg	25Jun2013	08Jul2013		
		01JUL2013	08OCT2013	Metohexal	METOPROLOL	ANALGESICS	Hypertonie Hypertension	47.5 mg	Aug2013		Yes	
		01JUL2013	08OCT2013	Rocephin	CEFTRIAXONE SODIUM	BETA BLOCKING AGENTS ANTIBACTERIALS FOR SYSTEMIC USE	Antibiose	1.5 g	08Oct2013	08Oct2013		
02/0207		24JUL2013	-	Ibuprofen 600 mg	IBUPROFEN	OTHER	Pain	1800 mg	23Jul2013		Yes	
		24JUL2013	-	Ibuprofen 600 mg	IBUPROFEN	GYNECOLOGICALS ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1800 mg	23Jul2013		Yes	
		24JUL2013	-	Ibuprofen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1800 mg	23Jul2013		Yes	
		24JUL2013	-	Ibuprofen 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain	1800 mg	23Jul2013		Yes	
		24JUL2013	-	Ibuprofen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain	1800 mg	23Jul2013		Yes	
		24JUL2013	-	Ortoton 750 mg	METHOCARBAMOL	MUSCLE RELAXANTS	Pain	4500 mg	23Jul2013		Yes	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0207		24JUL2013	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Prophylaxis	40 mg	23Jul2013		Yes	
		24JUL2013	-	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Antibiosis	1.5 g	24Jul2013	24Jul2013		
		24JUL2013	-	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Antibiosis	1.5 g	24Jul2013	24Jul2013		
02/0208	ND plus	12SEP2013	10DEC2013	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Stomach Prevention	40 mg	13Sep2013	Oct2013		
		12SEP2013	10DEC2013	Volon A (Triamcinolon 40 mg)	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Rezidiv L5/S1	1 ml = 40 mg	19Dec2013	19Dec2013		
		12SEP2013	10DEC2013	Volon A (Triamcinolon 40 mg)	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS /	Rezidiv L5/S1	1 ml = 40 mg	19Dec2013	19Dec2013		
		12SEP2013	10DEC2013	Volon A (Triamcinolon 40 mg)	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICA LS	Rezidiv L5/S1	1 ml = 40 mg	19Dec2013	19Dec2013		
		12SEP2013	10DEC2013	Volon A (Triamcinolon 40 mg)	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE	Rezidiv L5/S1	1 ml = 40 mg	19Dec2013	19Dec2013		
		12SEP2013	10DEC2013	Volon A (Triamcinolon 40 mg)	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Rezidiv L5/S1	1 ml = 40 mg	19Dec2013	19Dec2013		
		12SEP2013	10DEC2013	Volon A (Triamcinolon 40 mg)	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Rezidiv L5/S1	1 ml = 40 mg	19Dec2013	19Dec2013		
		12SEP2013	10DEC2013	Volon A (Triamcinolon 40 mg)	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Rezidiv L5/S1	1 ml = 40 mg	19Dec2013	19Dec2013		
		12SEP2013	10DEC2013	Pantoprazol (Pantoprazol)	PANTOPRAZOLE	DRUGS FOR ACID RELATED DISORDERS	Stomach Prevention	20 mg	02Apr2014	08Apr2014		
		12SEP2013	10DEC2013	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombosis prophylaxis	40 mg	13Sep2013	20Sep2013		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0208	ND plus	12SEP2013	10DEC2013	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombosis Prevention	40 mg	03Apr2014	07Apr2014	
		12SEP2013	10DEC2013	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Stomach prev	40 mg/day	21Sep2015	Oct2015	
		12SEP2013	10DEC2013	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	infection prophylaxis	1500 mg	12Sep2013	12Sep2013	
		12SEP2013	10DEC2013	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	infection prophylaxis	1500 mg	12Sep2013	12Sep2013	
		12SEP2013	10DEC2013	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Prevention swelling	24 mg	16Sep2013	18Sep2013	
		12SEP2013	10DEC2013	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Prevention swelling	24 mg	16Sep2013	18Sep2013	
		12SEP2013	10DEC2013	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS / DERMATOLOGICAL PREPARATIONS	Prevention swelling	24 mg	16Sep2013	18Sep2013	
		12SEP2013	10DEC2013	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Prevention swelling	24 mg	16Sep2013	18Sep2013	
		12SEP2013	10DEC2013	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Prevention swelling	24 mg	16Sep2013	18Sep2013	
		12SEP2013	10DEC2013	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	Prevention swelling	24 mg	16Sep2013	18Sep2013	
		12SEP2013	10DEC2013	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	Prevention swelling	24 mg	16Sep2013	18Sep2013	
		12SEP2013	10DEC2013	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	Prevention swelling	24 mg	16Sep2013	18Sep2013	
		12SEP2013	10DEC2013	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Prevention swelling	24 mg	16Sep2013	18Sep2013	
		12SEP2013	10DEC2013	Fortecortin	DEXAMETHASONE	OTOLOGICALS	Prevention swelling	24 mg	16Sep2013	18Sep2013	
		12SEP2013	10DEC2013	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Prevention swelling	24 mg	16Sep2013	18Sep2013	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0208	ND plus	12SEP2013	10DEC2013	Dexamethason	DEXAMETHASONE	VASOPROTECTIVES	Prevention swelling	4 mg	27Jul2015	01Aug2015	
		12SEP2013	10DEC2013	Dexamethason	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Prevention swelling	4 mg	27Jul2015	01Aug2015	
		12SEP2013	10DEC2013	Dexamethason	DEXAMETHASONE	OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	Prevention swelling	4 mg	27Jul2015	01Aug2015	
		12SEP2013	10DEC2013	Dexamethason	DEXAMETHASONE	OTOLOGICALS	Prevention swelling	4 mg	27Jul2015	01Aug2015	
		12SEP2013	10DEC2013	Dexamethason	DEXAMETHASONE	NASAL PREPARATIONS	Prevention swelling	4 mg	27Jul2015	01Aug2015	
		12SEP2013	10DEC2013	Dexamethason	DEXAMETHASONE	OPHTHALMOLOGICALS	Prevention swelling	4 mg	27Jul2015	01Aug2015	
		12SEP2013	10DEC2013	Dexamethason	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Prevention swelling	4 mg	27Jul2015	01Aug2015	
		12SEP2013	10DEC2013	Dexamethason	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Prevention swelling	4 mg	27Jul2015	01Aug2015	
		12SEP2013	10DEC2013	Dexamethason	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Prevention swelling	4 mg	27Jul2015	01Aug2015	
		12SEP2013	10DEC2013	Dexamethason	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Prevention swelling	4 mg	27Jul2015	01Aug2015	
		12SEP2013	10DEC2013	Dexamethason	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Prevention swelling	4 mg	27Jul2015	01Aug2015	
		12SEP2013	10DEC2013	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Stomach Prevention	40 mg	09Dec2013	14Dec2013	
		12SEP2013	10DEC2013	Diclofenac	DICLOFENAC	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	Anti-inflammatory	75 mg	27Jul2015	01Aug2015	
		12SEP2013	10DEC2013	Diclofenac	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Anti-inflammatory	75 mg	27Jul2015	01Aug2015	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0208	ND plus	12SEP2013	10DEC2013	Diclofenac	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Anti-inflammato ry	75 mg	27Jul2015	01Aug2015		
		12SEP2013	10DEC2013	Diclofenac	DICLOFENAC	OPHTHALMOLOGICA LS	Anti-inflammato ry	75 mg	27Jul2015	01Aug2015		
		12SEP2013	10DEC2013	Diclofenac	DICLOFENAC	THROAT PREPARATIONS	Anti-inflammato ry	75 mg	27Jul2015	01Aug2015		
		12SEP2013	10DEC2013	Diclofenac	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Anti-inflammato ry	75 mg	27Jul2015	01Aug2015		
		12SEP2013	10DEC2013	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thombosis prophylaxis	40 mg	10Dec2013	10Dec2013		
		12SEP2013	10DEC2013	Pantoprazol (Pantoprazol)	PANTOPRAZOLE	DRUGS FOR ACID RELATED DISORDERS	stomach prevention	40 mg	21Sep2015		Yes	
		12SEP2013	10DEC2013	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	stomach Prevention	20 mg	16Dec2013	Dec2013		
		12SEP2013	10DEC2013	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombosis Prevention	40 mg	23Sep2015	28Sep2015		
		12SEP2013	10DEC2013	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	infection prophylaxis	1.5 g	10Dec2013	10Dec2013		
		12SEP2013	10DEC2013	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	infection prophylaxis	1.5 g	10Dec2013	10Dec2013		
		12SEP2013	10DEC2013	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Antibiosis	1.5 g	22Sep2015	22Sep2015		
		12SEP2013	10DEC2013	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Antibiosis	1.5 g	22Sep2015	22Sep2015		
02/0209	ND plus	23OCT2014	30JAN2015	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: prevention stomach	20 mg	22Oct2014	Nov2014		
		23OCT2014	30JAN2015	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: prevention thrombosis	40 mg	24Oct2014	29Oct2014		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0210		13NOV2014	-	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic prophylaxis	2 g	13Nov2014	13Nov2014		
		13NOV2014	-	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: antibiotic prophylaxis	2 g	13Nov2014	13Nov2014		
02/0211	ND basic	11DEC2014	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Stomach preveniton	40 mg	10Dec2014	27Dec2014		
		11DEC2014	-	Keltican forte (Uridinmonophosph at + Vitamin B12 + Folic acid)	KELTICAN /06870301/	ANTIANEMIC PREPARATIONS	Other: nerval reconstruction	1 mg	02Jan2015	04Mar2015		
		11DEC2014	-	Clexane 40	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prevention	40 mg	12Dec2014	16Dec2014		
		11DEC2014	-	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: Simple Antibiosis	1.5 g	11Dec2014	11Dec2014		
		11DEC2014	-	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Simple Antibiosis	1.5 g	11Dec2014	11Dec2014		
		11DEC2014	-	Sirdalut	TIZANIDINE HYDROCHLORIDE	MUSCLE RELAXANTS	Other: muscle relaxant	6 mg	16Dec2014	27Dec2014		
02/0212	SC	16DEC2014	-	Antibiotic (name not known)	ANTIBIOTICS (90046601001)	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Staph. Infection (AE no. 01)	UNK	11Jan2016	17Jan2016		AE-1
		16DEC2014	-	Antibiotic (name not known)	ANTIBIOTICS (90046601001)	ANTIMYCOBACTERI ALS	Other: Staph. Infection (AE no. 01)	UNK	11Jan2016	17Jan2016		AE-1
		16DEC2014	-	Antibiotic (name not known)	ANTIBIOTICS (90046601001)	ANTIMYCOTICS FOR SYSTEMIC USE	Other: Staph. Infection (AE no. 01)	UNK	11Jan2016	17Jan2016		AE-1
		16DEC2014	-	Antibiotic (name not known)	ANTIBIOTICS (90046601001)	ANTIFUNGALS FOR DERMATOLOGICAL USE	Other: Staph. Infection (AE no. 01)	UNK	11Jan2016	17Jan2016		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0212	SC	16DEC2014	-	Antibiotic (name not known)	ANTIBIOTICS (90046601001)	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: Staph. Infection (AE no. 01)	UNK	11Jan2016	17Jan2016		AE-1
		16DEC2014	-	Antibiotic (name not known)	ANTIBIOTICS (90046601001)	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: Staph. Infection (AE no. 01)	UNK	11Jan2016	17Jan2016		AE-1
		16DEC2014	-	Antibiotic (name not known)	ANTIBIOTICS (90046601001)	OPHTHALMOLOGICA LS	Other: Staph. Infection (AE no. 01)	UNK	11Jan2016	17Jan2016		AE-1
		16DEC2014	-	Antibiotic (name not known)	ANTIBIOTICS (90046601001)	THROAT PREPARATIONS	Other: Staph. Infection (AE no. 01)	UNK	11Jan2016	17Jan2016		AE-1
		16DEC2014	-	Antibiotic (name not known)	ANTIBIOTICS (90046601001)	VASOPROTECTIVES	Other: Staph. Infection (AE no. 01)	UNK	11Jan2016	17Jan2016		AE-1
		16DEC2014	-	Antibiotic (name not known)	ANTIBIOTICS (90046601001)	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: Staph. Infection (AE no. 01)	UNK	11Jan2016	17Jan2016		AE-1
		16DEC2014	-	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ulcer prevention (stomach ache)	40 mg	15Dec2014	23Dec2014		
		16DEC2014	-	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prevention	40 mg	17Dec2014	20Dec2014		
		16DEC2014	-	Ceforoxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: single shoot antibiosis prevention	500 mg	16Dec2014	16Dec2014		
		16DEC2014	-	Ceforoxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: single shoot antibiosis prevention	500 mg	16Dec2014	16Dec2014		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0213	ND plus	18DEC2014	-	Pantoprazol (Pantoprazol)	PANTOPRAZOLE	DRUGS FOR ACID RELATED DISORDERS	Other: Gastric ulcer prevention	20 mg	17Dec2014	UNK	
		18DEC2014	-	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: antibiotics treatment	1.5 g	18Dec2014	18Dec2014	
		18DEC2014	-	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotics treatment	1.5 g	18Dec2014	18Dec2014	
		18DEC2014	-	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombosis prevention	40 mg	17Dec2014	UNK	
02/0214	ND plus	25FEB2015	28MAY2015	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: stomach prevention	20 mg	24Feb2015	Mar2015	
		25FEB2015	28MAY2015	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombose Prophylaxis	40 mg	24Feb2015	02Mar2015	
		25FEB2015	28MAY2015	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: antibiotics treatment	1.5 g	25Feb2015	25Feb2015	
		25FEB2015	28MAY2015	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotics treatment	1.5 g	25Feb2015	25Feb2015	
02/0215		-	-	Ceforoxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: OP - related single shoot antibiosis	1.5 g	05Mar2015	05Mar2015	
		-	-	Ceforoxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: OP - related single shoot antibiosis	1.5 g	05Mar2015	05Mar2015	
		-	-	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: stomach prevention	20 mg	04Mar2015	Mar2015	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0216	ND plus	28APR2015	23JUL2015	L-Thyroxin	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyroidism	137 mg	May2015		Yes	
		28APR2015	23JUL2015	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: gastic ulcer prevention	20 mg	27Apr2015	May2015		
		28APR2015	23JUL2015	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: infection prevention	1500 mg	28Apr2015	28Apr2015		
		28APR2015	23JUL2015	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: infection prevention	1500 mg	28Apr2015	28Apr2015		
		28APR2015	23JUL2015	Clexane 40	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prevention	40 mg	27Apr2015	05May2015		
02/0217	SC	28MAY2015	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: stomach prevention	20 mg	26May2015	07Jun2015		
		28MAY2015	-	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: stomach prevention	40 mg	May2015	26May2015		
		28MAY2015	-	Ceftriaxon	CEFTRIAZONE SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic prophylaxis	2 g	28May2015	28May2015		
		28MAY2015	-	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prevention	40 mg	26May2015	04Jun2015		
02/0218	ND basic	30JUN2015	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: stomach prevention	40 mg	30Jun2015		Yes	
		30JUN2015	-	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: antibiotics treatment	1.5 g	30Jun2015	30Jun2015		
		30JUN2015	-	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotics treatment	1.5 g	30Jun2015	30Jun2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0218	ND basic	30JUN2015	-	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombosis prevention	40 mg	30Jun2015	04Jul2015		
02/0219	ND basic	11JUN2015	25SEP2015	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Stomach prevention	40 mg	10Jun2015	12Jul2015		
		11JUN2015	25SEP2015	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombosis prevention	40 mg	26Sep2015	26Sep2015		
		11JUN2015	25SEP2015	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Stomach prevention	40 mg	24Sep2015	03Oct2015		
		11JUN2015	25SEP2015	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombosis prevention	40 mg	10Jun2015	18Jun2015		
		11JUN2015	25SEP2015	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: antibiotics treatment	1.5 g	11Jun2015	11Jun2015		
		11JUN2015	25SEP2015	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotics treatment	1.5 g	11Jun2015	11Jun2015		
02/0220	SC	13AUG2015	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: stomach prophylaxis	20 mg	12Aug2015	Sep2015		
		13AUG2015	-	Paracetamol	PARACETAMOL	ANALGESICS	Other: AE 1 (AE no. 01)	1000 mg	Apr2019	Apr2019		AE-1
		13AUG2015	-	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis	40 mg	12Aug2015	20Aug2015		
		13AUG2015	-	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: antibiotic treatment	1.5 g	13Aug2015	13Aug2015		
		13AUG2015	-	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic treatment	1.5 g	13Aug2015	13Aug2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0221	ND plus	01SEP2015	-	Meto-Saccinat ret. 23.75	METOPROLOL SUCCINATE	BETA BLOCKING AGENTS	Other: Tachycardia (MedHis no. 01)	1x23.75	Dec2014	Sep2015		MH-1
		01SEP2015	-	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prevention	40 mg	31Aug2015	02Sep2015		
		01SEP2015	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: stomach prevention	40 mg	17Aug2015	Sep2015		
		01SEP2015	-	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: antibiotic prophylaxis	1.5 g	01Sep2015	01Sep2015		
		01SEP2015	-	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic prophylaxis	1.5 g	01Sep2015	01Sep2015		
02/0222	ND plus	10SEP2015	-	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Antibiosis	1.5 g	10Sep2015	10Sep2015		
		10SEP2015	-	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: Antibiosis	1.5 g	10Sep2015	10Sep2015		
		10SEP2015	-	Clexane 40	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Prevention Thrombosis	40	30Aug2015	09Sep2015		
		10SEP2015	-	Movicol	OSMOTICALLY ACTING LAXATIVES (90062401001)	DRUGS FOR CONSTIPATION	Other: Obstipation prevention	13.75	09Sep2015	15Sep2015		
		10SEP2015	-	Meto Hexal 190 mg	METOPROLOL	BETA BLOCKING AGENTS	Other: Hypertension (MedHis no. 01)	95 mg	1995		Yes	MH-1
		10SEP2015	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Stomach prevention	2 mg	09Sep2015		Yes	
		10SEP2015	-	Enahexal (Enalapril maleat 10 mg)	ENALAPRIL MALEATE	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Other: Hypertension (MedHis no. 01)	5 mg	2007		Yes	MH-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0223	ND basic	29DEC2015	22MAR2016	Venlafaxin	VENLAFAXINE HYDROCHLORIDE	ANALGESICS	Other: Depression (MedHis no. 02)	150 mg	2013		Yes	MH-2
		29DEC2015	22MAR2016	Venlafaxin	VENLAFAXINE HYDROCHLORIDE	PSYCHOANALEPTIC S	Other: Depression (MedHis no. 02)	150 mg	2013		Yes	MH-2
		29DEC2015	22MAR2016	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: stomach prevention	20 mg	01Jan2016	03Mar2021		
		29DEC2015	22MAR2016	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Other: shoulder pain (AE no. 02)	600 mg as needed	May2016	03Mar2021		AE-2
		29DEC2015	22MAR2016	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Other: shoulder pain (AE no. 02)	600 mg as needed	May2016	03Mar2021		AE-2
		29DEC2015	22MAR2016	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: shoulder pain (AE no. 02)	600 mg as needed	May2016	03Mar2021		AE-2
		29DEC2015	22MAR2016	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: shoulder pain (AE no. 02)	600 mg as needed	May2016	03Mar2021		AE-2
		29DEC2015	22MAR2016	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Other: shoulder pain (AE no. 02)	600 mg as needed	May2016	03Mar2021		AE-2
		29DEC2015	22MAR2016	Novaminsulfon	METAMIZOLE SODIUM	ANALGESICS	Other: SAE 02.05 (AE no. 05)	4 x 500 mg	Jan2018	03Mar2021		AE-5
		29DEC2015	22MAR2016	Teufelskralle	HARPAGOPHYTUM PROCUMBENS ROOT	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	Other: AE07 (AE no. 07)	as needed	2020		Yes	AE-7
		29DEC2015	22MAR2016	Loratadin	LORATADINE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: allergy prophylaxis allergic rhinitis (AE no. 01)	10 mg as needed	01Apr2016		Yes	AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0223	ND basic	29DEC2015	22MAR2016	Tilidin	VALORON N	ANALGESICS	Other: SAE 02.05 (AE no. 05)	2 x 50 mg	Jan2018	03Mar2021		AE-5
		29DEC2015	22MAR2016	Clexane	/00628301/ ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prevention	40 mg	30Dec2015	04Jan2016		
		29DEC2015	22MAR2016	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: stomach prevention	20 mg	21Mar2016	01Apr2016		
02/0224	ND plus	29DEC2015	-	Ceforoxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: infection prevention	single shoot 1500 mg	29Dec2015	29Dec2015		
		29DEC2015	-	Ceforoxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: infection prevention	single shoot 1500 mg	29Dec2015	29Dec2015		
		29DEC2015	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: prevention stomach (MedHis no. 01)	40 mg	27Dec2015	03Jan2016		MH-1
		29DEC2015	-	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: prevention thrombosis	40 mg	27Dec2015	03Jan2016		
04/0401	SC	30JUN2015 30JUN2015	- -	Remifentanyl Pantozol (Pantoprazol) 40 mg	REMIFENTANIL PANTOPRAZOLE SODIUM SESQUIHYDRATE	ANESTHETICS DRUGS FOR ACID RELATED DISORDERS	Other: TIVA Other: protection of stomach during Ibuprofen (MedHis no. 08)	GA, TIVA 1-0-0	30Jun2015 01May2015	30Jun2015 30Jun2015		MH-8
		30JUN2015	-	Rocuronium	ROCURONIUM	MUSCLE RELAXANTS	Other: ITN	50 mg	30Jun2015	30Jun2015		
		30JUN2015	-	Cefazolin 2 g	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: routine presurgical antibiosis	1x1	30Jun2015	30Jun2015		
		30JUN2015	-	Piritramid	PIRITRAMIDE	ANALGESICS	Other: post op pain relief	5 mg	30Jun2015	30Jun2015		
		30JUN2015	-	Propofol	PROPOFOL	ANESTHETICS	Other: anaesthesia	during surgery	30Jun2015	30Jun2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
04/0401	SC	30JUN2015	-	Noradrenaline	NOREPINEPHRINE	CARDIAC THERAPY	Other: blood pressure increased under general anaesthesia	cont. infusion	30Jun2015	30Jun2015		
06/0602	ND plus	23JUL2013	05NOV2013	Paroxetin	PAROXETINE	PSYCHOANALEPTIC S	Depression	40 mg	1998		Yes	
		23JUL2013	05NOV2013	Paroxetin	PAROXETINE	PSYCHOANALEPTIC S	Other: Depression	20 mg	Apr2015		Yes	
		23JUL2013	05NOV2013	L-Tyroxin	LEVOTHYROXINE SODIUM	THYROID THERAPY	Hypothyreodism	100 ug	2011		Yes	
		23JUL2013	05NOV2013	Lamotrigin	LAMOTRIGINE	ANTIEPILEPTICS	Other: Depression	200 mg	Apr2015		Yes	
		23JUL2013	05NOV2013	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Stomach Protection	20 mg	23Jul2013	12Aug2013		
		23JUL2013	05NOV2013	Mono Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Thrombosis Prophylaxis	3000 iu	22Jul2013	27Jul2013		
		23JUL2013	05NOV2013	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICALS	preoperative antibiotics prophylaxis	1.5 g	23Jul2013	23Jul2013		
		23JUL2013	05NOV2013	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	preoperative antibiotics prophylaxis	1.5 g	23Jul2013	23Jul2013		
06/0604	ND basic	28OCT2014	-	Diclofenac 75 mg	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other	75 mg	13Oct2014	20Oct2014		
		28OCT2014	-	Diclofenac 75 mg	DICLOFENAC	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	Pain-other	75 mg	13Oct2014	20Oct2014		
		28OCT2014	-	Diclofenac 75 mg	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-other	75 mg	13Oct2014	20Oct2014		
		28OCT2014	-	Diclofenac 75 mg	DICLOFENAC	OPHTHALMOLOGICALS	Pain-other	75 mg	13Oct2014	20Oct2014		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0604	ND basic	28OCT2014	-	Diclofenac 75 mg	DICLOFENAC	THROAT PREPARATIONS	Pain-other	75 mg	13Oct2014	20Oct2014		
		28OCT2014	-	Diclofenac 75 mg	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-other	75 mg	13Oct2014	20Oct2014		
		28OCT2014	-	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-other	1 g	23Oct2014		Yes	
		28OCT2014	-	Perfalgan	PARACETAMOL	ANALGESICS	Pain-other	1 ug	23Oct2014	24Oct2014		
		28OCT2014	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-other	600 mg	20Oct2014	23Oct2014		
		28OCT2014	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-other	600 mg	20Oct2014	23Oct2014		
		28OCT2014	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other	600 mg	20Oct2014	23Oct2014		
		28OCT2014	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other	600 mg	20Oct2014	23Oct2014		
		28OCT2014	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other	600 mg	20Oct2014	23Oct2014		
		28OCT2014	-	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Other: Pain, decongestant action	4 mg	23Oct2014	27Oct2014		
		28OCT2014	-	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Pain, decongestant action	4 mg	23Oct2014	27Oct2014		
		28OCT2014	-	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Pain, decongestant action	4 mg	23Oct2014	27Oct2014		
		28OCT2014	-	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Other: Pain, decongestant action	4 mg	23Oct2014	27Oct2014		
		28OCT2014	-	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	Other: Pain, decongestant action	4 mg	23Oct2014	27Oct2014		
		28OCT2014	-	Fortecortin	DEXAMETHASONE	OTOLOGICALS	Other: Pain, decongestant action	4 mg	23Oct2014	27Oct2014		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
06/0604	ND basic	28OCT2014	-	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Pain, decongestant action	4 mg	23Oct2014	27Oct2014	
		28OCT2014	-	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	Other: Pain, decongestant action	4 mg	23Oct2014	27Oct2014	
		28OCT2014	-	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: Pain, decongestant action	4 mg	23Oct2014	27Oct2014	
		28OCT2014	-	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: Pain, decongestant action	4 mg	23Oct2014	27Oct2014	
		28OCT2014	-	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	Other: Pain, decongestant action	4 mg	23Oct2014	27Oct2014	
		28OCT2014	-	Mono Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombo-prophyl axis	0.3	23Oct2014	01Nov2014	
		28OCT2014	-	Diclofenac 7	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other	75 mg	23Oct2014	Jan2015	
		28OCT2014	-	Diclofenac 7	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other	75 mg	23Oct2014	Jan2015	
		28OCT2014	-	Diclofenac 7	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-other	75 mg	23Oct2014	Jan2015	
		28OCT2014	-	Diclofenac 7	DICLOFENAC	THROAT PREPARATIONS	Pain-other	75 mg	23Oct2014	Jan2015	
		28OCT2014	-	Diclofenac 7	DICLOFENAC	OPHTHALMOLOGICA LS	Pain-other	75 mg	23Oct2014	Jan2015	
		28OCT2014	-	Diclofenac 7	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-other	75 mg	23Oct2014	Jan2015	
		28OCT2014	-	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: Antibiotics	1.5 g	28Oct2014	28Oct2014	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0604	ND basic	28OCT2014	-	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Antibiotics	1.5 g	28Oct2014	28Oct2014		
		28OCT2014	-	Tramal (Tramadolhydrochl orid)	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-other	100 mg	23Oct2014	27Oct2014		
		28OCT2014	-	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Protection of the stomach	20 mg	23Oct2014	Jan2015		
06/0605	ND plus	11DEC2014	-	Doxepin 100 mg	DOXEPIN	PSYCHOLEPTICS	Other: chronic Depression	100 mg/1	2009		Yes	
		11DEC2014	-	Doxepin 100 mg	DOXEPIN	PSYCHOANALEPTIC S	Other: chronic Depression	100 mg/1	2009		Yes	
		11DEC2014	-	Doxepin 100 mg	DOXEPIN	ANTIPRURITICS, INCL. ANTI HISTAMINES, ANESTHETICS, ETC.	Other: chronic Depression	100 mg/1	2009		Yes	
		11DEC2014	-	Fluoxetin 20 mg	FLUOXETINE HYDROCHLORIDE	PSYCHOANALEPTIC S	Other: chronic Depression	20 mg/1	2009		Yes	
		11DEC2014	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Protection of the stomach	20 mg	11Dec2014		Yes	
		11DEC2014	-	Bisoprolol 10 mg	BISOPROLOL	BETA BLOCKING AGENTS	Other: Hypertension	5 mg/1	2004		Yes	
		11DEC2014	-	Mono Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis	0.3	10Dec2014	18Dec2014		
		11DEC2014	-	Cefuroxim 1.5 g	CEFUROXIME	OPHTHALMOLOGICA LS	Other: Antibiotics	1.5 g 1	11Dec2014	11Dec2014		
		11DEC2014	-	Cefuroxim 1.5 g	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Antibiotics	1.5 g 1	11Dec2014	11Dec2014		
		11DEC2014	-	Zolpidem	ZOLPIDEM	PSYCHOLEPTICS	Other: Sleep aid prophylactic	10 mg	10Dec2014	16Dec2014		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0606	SC	16DEC2014	-	Cefuroxim 1.5 g	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: prevention	1.5 g/1	16Dec2014	16Dec2014		
		16DEC2014	-	Cefuroxim 1.5 g	CEFUROXIME	OPHTHALMOLOGICA LS	Other: prevention	1.5 g/1	16Dec2014	16Dec2014		
		16DEC2014	-	Mono Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Prophylaxis	0.3 mg	15Dec2014	Jan2015		
		16DEC2014	-	Seroquel	QUETIAPINE FUMARATE	PSYCHOLEPTICS	Other: Depression (AE no. 16)	25 mg	18Dec2014	07Jul2015		AE-16
		16DEC2014	-	Metformin	METFORMIN	DRUGS USED IN DIABETES	Other: Diabetes Mellitus (AE no. 15)	2000 mg/2	Jan2015		Yes	AE-15
		16DEC2014	-	Bydureon	EXENATIDE	DRUGS USED IN DIABETES	Other: Diabetes (AE no. 15)	2 mg a week	16Oct2015	01Dec2015		AE-15
		16DEC2014	-	Symbioflor 1	ENTEROCOCCUS FAECALIS	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: bowel cleanse (AE no. 07)	UNK	Nov2015	18Nov2015		AE-7
		16DEC2014	-	Posiformin 2% Bibrocatol	BIBROCATHOL	OPHTHALMOLOGICA LS	Other: hordeolum (AE no. 11)	1 eye drop	18Jul2016	20Jul2016		AE-11
		16DEC2014	-	Metamizol	METAMIZOLE	ANALGESICS	Pain-other (AE no. 23)	1000 mg 2x per week	04Mar2018		Yes	AE-23
		16DEC2014	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: prophylaxis	80 mg	2014		Yes	
		16DEC2014	-	Zolpidem	ZOLPIDEM	PSYCHOLEPTICS	Other: sleeping during hospital stay	10 mg	17Dec2014	17Dec2014		
		16DEC2014	-	Lactulose	LACTULOSE	DRUGS FOR CONSTIPATION	Other: prophylaxis	UNK	17Dec2014	19Dec2014		
		16DEC2014	-	Lactulose	LACTULOSE	BILE AND LIVER THERAPY	Other: prophylaxis	UNK	17Dec2014	19Dec2014		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0606	SC	16DEC2014	-	Euthyrox	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyroidism (AE no. 06)	25 mg	08Nov2015		Yes	AE-6
		16DEC2014	-	Symbioflor 2	ESCHERICHIA COLI	OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	Other: bowel cleanse (AE no. 07)	UNK	19Nov2015	Jan2016		AE-7
		16DEC2014	-	Symbioflor 2	ESCHERICHIA COLI	VASOPROTECTIVES	Other: bowel cleanse (AE no. 07)	UNK	19Nov2015	Jan2016		AE-7
		16DEC2014	-	Symbioflor 2	ESCHERICHIA COLI	UROLOGICALS	Other: bowel cleanse (AE no. 07)	UNK	19Nov2015	Jan2016		AE-7
		16DEC2014	-	Doxylaminsuccinat	DOXYLAMINE SUCCINATE	PSYCHOLEPTICS	Other: Insomnia (AE no. 08)	30 mg	Feb2016		Yes	AE-8
		16DEC2014	-	Doxylaminsuccinat	DOXYLAMINE SUCCINATE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: Insomnia (AE no. 08)	30 mg	Feb2016		Yes	AE-8
		16DEC2014	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 13)	600 mg	30Aug2016	31Aug2016		AE-13
		16DEC2014	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 13)	600 mg	30Aug2016	31Aug2016		AE-13
		16DEC2014	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 13)	600 mg	30Aug2016	31Aug2016		AE-13
		16DEC2014	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 13)	600 mg	30Aug2016	31Aug2016		AE-13
		16DEC2014	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 13)	600 mg	30Aug2016	31Aug2016		AE-13
		16DEC2014	-	Opipramol	OPIPRAMOL	PSYCHOANALEPTIC S	Other: Insomnia (AE no. 08)	100 mg	09Oct2018		Yes	AE-8

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0606	SC	16DEC2014	-	Metoclopramid	METOCLOPRAMIDE	DRUGS FOR FUNCTIONAL GASTROINTESTINA L DISORDERS	Other: nausea (AE no. 14)	UNK	18Dec2014	18Dec2014		AE-14
		16DEC2014	-	Doxylaminsuccinat	DOXYLAMINE SUCCINATE	PSYCHOLEPTICS	Other: insomnia	37.5 mg	2013	Nov2015		
		16DEC2014	-	Doxylaminsuccinat	DOXYLAMINE SUCCINATE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: insomnia	37.5 mg	2013	Nov2015		
		16DEC2014	-	Melatonin	MELATONIN	HOMEOPATHIC PREPARATION	Other: Insomnia (AE no. 08)	5 mg	Nov2015	Feb2016		AE-8
		16DEC2014	-	Melatonin	MELATONIN	PSYCHOLEPTICS	Other: Insomnia (AE no. 08)	5 mg	Nov2015	Feb2016		AE-8
		16DEC2014	-	Trimipramin	TRIMIPRAMINE	PSYCHOANALEPTIC S	Other: Depression (AE no. 12)	UNK	20Oct2015	23Nov2016		AE-12
		16DEC2014	-	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: bacterial infection (AE no. 28)	1000 mg	16Oct2019	26Oct2019		AE-28
		16DEC2014	-	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: bacterial infection (AE no. 28)	1000 mg	16Oct2019	26Oct2019		AE-28
		16DEC2014	-	Zofran	ONDANSETRON	ANTIEMETICS AND ANTINAUSEANTS	Other: nausea (AE no. 14)	2 mg	19Dec2014	19Dec2014		AE-14
		16DEC2014	-	Symbioflor Pro	PROSYMBIOFLOR	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: bowel cleanse (AE no. 07)	UNK	19Oct2015	Nov2015		AE-7
		16DEC2014	-	Prosan immun Vitaminkomplex	MULTIVITAMINS, PLAIN (90004001001)	VITAMINS	Other: Prophylaxis	UNK	07Sep2016		Yes	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0607	ND plus	20JAN2015	15APR2015	Omeprazol	OMEPRAZOLE	DRUGS FOR ACID RELATED DISORDERS	Other: prophylaxis (MedHis no. 01)	20 mg	2010		Yes	MH-1
		20JAN2015	15APR2015	Zolpidem	ZOLPIDEM	PSYCHOLEPTICS	Other: sleeping	10 mg	20Jan2015	20Jan2015		
		20JAN2015	15APR2015	Azithromycin	AZITHROMYCIN	OPHTHALMOLOGICA LS	Other: Infection (AE no. 02)	500 mg/d	14Jul2015	16Jul2015		AE-2
		20JAN2015	15APR2015	Azithromycin	AZITHROMYCIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Infection (AE no. 02)	500 mg/d	14Jul2015	16Jul2015		AE-2
		20JAN2015	15APR2015	Azithromycin	AZITHROMYCIN	ANTI-ACNE PREPARATIONS	Other: Infection (AE no. 02)	500 mg/d	14Jul2015	16Jul2015		AE-2
		20JAN2015	15APR2015	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Antibiotics (AE no. 03)	1000 mg	Dec2016	Jan2017		AE-3
		20JAN2015	15APR2015	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: Antibiotics (AE no. 03)	1000 mg	Dec2016	Jan2017		AE-3
		20JAN2015	15APR2015	Levothyroxin-Natr ium	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyroidism (AE no. 06)	50 mg	01Jan2017	30Apr2018		AE-6
		20JAN2015	15APR2015	Magnesium	MAGNESIUM	MINERAL SUPPLEMENTS	Other: muscle cramp (AE no. 07)	40 mg	Feb2017	Mar2017		AE-7
		20JAN2015	15APR2015	Levothyroxin	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyreose (AE no. 06)	75 mg	01May2018		Yes	AE-6
		20JAN2015	15APR2015	Pylera 140/125/125 mg	PYLERA	DRUGS FOR ACID RELATED DISORDERS	Other: Helicobacter pylori (AE no. 14)	1680 mg/1500 mg/1500 mg	17Feb2019	28Feb2019		AE-14
		20JAN2015	15APR2015	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: Antibiotics	1.5 g	20Jan2015	20Jan2015		
		20JAN2015	15APR2015	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Antibiotics	1.5 g	20Jan2015	20Jan2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0607	ND plus	20JAN2015	15APR2015	Riopan (Magaldrat)	MAGALDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Heartburn	1600 mg	21Jan2015	21Jan2015		
		20JAN2015	15APR2015	Doxycyclin	DOXYCYCLINE	STOMATOLOGICAL PREPARATIONS	Other: Antibiotics (AE no. 04)	400 mg	Jun2016	Jul2016		AE-4
		20JAN2015	15APR2015	Doxycyclin	DOXYCYCLINE	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Antibiotics (AE no. 04)	400 mg	Jun2016	Jul2016		AE-4
		20JAN2015	15APR2015	Doxycyclin	DOXYCYCLINE	ANTI-ACNE PREPARATIONS	Other: Antibiotics (AE no. 04)	400 mg	Jun2016	Jul2016		AE-4
		20JAN2015	15APR2015	Doxycyclin	DOXYCYCLINE	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: Antibiotics (AE no. 04)	400 mg	Jun2016	Jul2016		AE-4
		20JAN2015	15APR2015	Atorvastatin	ATORVASTATIN	LIPID MODIFYING AGENTS	Other: Prophylaxis	20 mg	01Oct2016	31Dec2016		
		20JAN2015	15APR2015	Paracetamol	PARACETAMOL	ANALGESICS	Other: Common cold (AE no. 10)	1500 mg	Oct2017	Oct2017		AE-10
		20JAN2015	15APR2015	Ibuprofen/Pseudoephedrinhydrochlorid	CO-ADVIL	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	Other: Common cold (AE no. 12)	200 mg/30 mg	27Jun2018	30Jun2018		AE-12
		20JAN2015	15APR2015	Pylera 140/125/125 mg	PYLERA	DRUGS FOR ACID RELATED DISORDERS	Other: Helicobacter pylori (AE no. 15)	1680 mg/1500 mg/1500 mg	Sep2019	Sep2019		AE-15
		20JAN2015	15APR2015	Prednisolon	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Tinnitus (AE no. 05)	50 mg	Jan2017	Jan2017		AE-5
		20JAN2015	15APR2015	Prednisolon	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Tinnitus (AE no. 05)	50 mg	Jan2017	Jan2017		AE-5

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing? MH/AE
06/0607	ND plus	20JAN2015	15APR2015	Prednisolon	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: Tinnitus (AE no. 05)	50 mg	Jan2017	Jan2017	AE-5
		20JAN2015	15APR2015	Prednisolon	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: Tinnitus (AE no. 05)	50 mg	Jan2017	Jan2017	AE-5
		20JAN2015	15APR2015	Prednisolon	PREDNISOLONE	VASOPROTECTIVES	Other: Tinnitus (AE no. 05)	50 mg	Jan2017	Jan2017	AE-5
		20JAN2015	15APR2015	Prednisolon	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Tinnitus (AE no. 05)	50 mg	Jan2017	Jan2017	AE-5
		20JAN2015	15APR2015	Prednisolon	PREDNISOLONE	OTOLOGICALS	Other: Tinnitus (AE no. 05)	50 mg	Jan2017	Jan2017	AE-5
		20JAN2015	15APR2015	Prednisolon	PREDNISOLONE	OPHTHALMOLOGICA LS	Other: Tinnitus (AE no. 05)	50 mg	Jan2017	Jan2017	AE-5
		20JAN2015	15APR2015	Prednisolon	PREDNISOLONE	NASAL PREPARATIONS	Other: Tinnitus (AE no. 05)	50 mg	Jan2017	Jan2017	AE-5
		20JAN2015	15APR2015	Ginko biloba leaves	GINKGO BILOBA LEAF	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	Other: Prophylaxis	UNK	01Oct2016	31Dec2016	
		20JAN2015	15APR2015	Cineol	CINEOLE	COUGH AND COLD PREPARATIONS	Other: Common cold (AE no. 12)	200 mg	27Jun2018	10Jul2018	AE-12
		20JAN2015	15APR2015	Mono Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: prophylaxis	0.3 mg	15Jan2015	26Jan2015	
		20JAN2015	15APR2015	Levothyroxin-Natr ium	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyroidism (AE no. 06)	25 mg	01Oct2016	31Dec2016	AE-6

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0607	ND plus	20JAN2015	15APR2015	Roxythromycin	ROXITHROMYCIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: bacterial pharyngeal Infection (AE no. 13)	300 mg	18Nov2018	27Nov2018		AE-13
06/0608	SC	29JAN2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other	1800 mg/600 mg	25Jan2015		Yes	
		29JAN2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other	1800 mg/600 mg	25Jan2015		Yes	
		29JAN2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other	1800 mg/600 mg	25Jan2015		Yes	
		29JAN2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-other	1800 mg/600 mg	25Jan2015		Yes	
		29JAN2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-other	1800 mg/600 mg	25Jan2015		Yes	
		29JAN2015	-	Tolperison	TOLPERISONE	MUSCLE RELAXANTS	Pain-other	150 mg/50 mg	25Jan2015	01Feb2015		
		29JAN2015	-	Tolperison	TOLPERISONE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other	150 mg/50 mg	25Jan2015	01Feb2015		
		29JAN2015	-	MCP	METOCLOPRAMIDE	DRUGS FOR FUNCTIONAL GASTROINTESTINA L DISORDERS	Other: Nausea	30 mg/10 mg	25Jan2015	29Jan2015		
		29JAN2015	-	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Prophylactic	20 mg	25Jan2015	Feb2015		
		29JAN2015	-	Novalgine (Novaminsulfon)	METAMIZOLE SODIUM	ANALGESICS	Pain-other	3 g/1 g	25Jan2015	01Feb2015		
		29JAN2015	-	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: Antibiotics	1.5 g	29Jan2015	29Jan2015		
		29JAN2015	-	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Antibiotics	1.5 g	29Jan2015	29Jan2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0609	ND basic	16APR2015	-	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Infection prevention	1.5 g/d	16Apr2015	16Apr2015		
		16APR2015	-	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: Infection prevention	1.5 g/d	16Apr2015	16Apr2015		
		16APR2015	-	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Protection/Prop hylaxis	20 mg	18Apr2015		Yes	
		16APR2015	-	Targin	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-other	10 mg	18Apr2015		Yes	
		16APR2015	-	Targin	TARGIN	ANALGESICS	Pain-other	10 mg	18Apr2015		Yes	
		16APR2015	-	Mono Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Antithrombosis	3000 IE	15Apr2015	21Apr2015		
		16APR2015	-	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-other (MedHis no. 01)	75 gtt	07Apr2015	20Apr2015		MH-1
		16APR2015	-	Targin	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-other (MedHis no. 01)	15 mg	07Apr2015	17Apr2015		MH-1
		16APR2015	-	Targin	TARGIN	ANALGESICS	Pain-other (MedHis no. 01)	15 mg	07Apr2015	17Apr2015		MH-1
06/0610	ND plus	16APR2015	-	Ebastin	EBASTINE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: hay fever	20 mg	UNK		Yes	
		25JUN2015	08SEP2015	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Infection prevention	1.5 g/d	25Jun2015	25Jun2015		
		25JUN2015	08SEP2015	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: Infection prevention	1.5 g/d	25Jun2015	25Jun2015		
		25JUN2015	08SEP2015	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Prophylaxis (AE no. 05)	40 mg	08Jan2016	18Jan2016		AE-5
		25JUN2015	08SEP2015	Zolpidem	ZOLPIDEM	PSYCHOLEPTICS	Other: sleeping	10 mg	19Jan2016	24Jan2016		
		25JUN2015	08SEP2015	L-Thyroxin mcg	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyriosis (MedHis no. 01)	75 mcg/d	2010		Yes	MH-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0610	ND plus	25JUN2015	08SEP2015	Mono Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombosis Prevention	3000 IU/d	25Jun2015	30Jun2015		
		25JUN2015	08SEP2015	Paracetamol	PARACETAMOL	ANALGESICS	Pain-other	1000 mg	19Jan2016	19Jan2016		
		25JUN2015	08SEP2015	Citalopram	CITALOPRAM	PSYCHOANALEPTIC S	Other: Antidepression med. (MedHis no. 02)	20 mg/d	2014	Dec2015		MH-2
		25JUN2015	08SEP2015	Stilnox	ZOLPIDEM TARTRATE	PSYCHOLEPTICS	Other: Sleeping aid	10 mg/d	24Jul2015	24Jul2015		
		25JUN2015	08SEP2015	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Prophylaxis	20 mg	20Jan2016	11Mar2016		
		25JUN2015	08SEP2015	Klysma salinisch	KLYSMA SALINISCH	DRUGS FOR CONSTIPATION	Other: obstipation	135 ml	20Jan2016	20Jan2016		
		25JUN2015	08SEP2015	Stilnox	/07140801/ ZOLPIDEM TARTRATE	PSYCHOLEPTICS	Other: Sleeping Aid	10 mg/d	28Jun2015	29Jun2015		
		25JUN2015	08SEP2015	Amitriptylin	AMITRIPTYLINE HYDROCHLORIDE	PSYCHOANALEPTIC S	Other: Depressiva (AE no. 05)	25 mg	08Jan2016	18Jan2016		AE-5
		25JUN2015	08SEP2015	Amitriptylin	AMITRIPTYLINE HYDROCHLORIDE	ANALGESICS	Other: Depressiva (AE no. 05)	25 mg	08Jan2016	18Jan2016		AE-5
		25JUN2015	08SEP2015	Mono Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Prophylaxis	3000 IE	21Jan2016	25Jan2016		
		25JUN2015	08SEP2015	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Prophylaxis	20 mg	20Jan2016	11Mar2016		
06/0611		15JUL2015	-	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Infection prevention	1.5 g/d	15Jul2015	15Jul2015		
		15JUL2015	-	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: Infection prevention	1.5 g/d	15Jul2015	15Jul2015		
		15JUL2015	-	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-other	300 mg	12Jul2015	19Jul2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0611		15JUL2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-other	1200 mg/d	12Jul2015		Yes	
		15JUL2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-other	1200 mg/d	12Jul2015		Yes	
		15JUL2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other	1200 mg/d	12Jul2015		Yes	
		15JUL2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other	1200 mg/d	12Jul2015		Yes	
		15JUL2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other	1200 mg/d	12Jul2015		Yes	
		15JUL2015	-	Mono Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombosis Prophylaxis	3000 IU	13Jul2015	19Jul2015		
		15JUL2015	-	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Protection of the stomach	40 mg/d	12Jul2015		Yes	
		15JUL2015	-	Capros	MORPHINE SULFATE	ANALGESICS	Pain-other	10 mg/d	13Jul2015	14Jul2015		
		15JUL2015	-	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-other	200 mg/d	12Jul2015	12Jul2015		
		15JUL2015	-	Zolpidem	ZOLPIDEM	PSYCHOLEPTICS	Other: sleeping aid	10 mg/d	14Jul2015	14Jul2015		
06/0612	ND plus	15JUL2015	20OCT2015	Symbicort	BUDESONIDE W/FORMOTEROL FUMARATE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: Bronchial System (MedHis no. 3)	2 Puff Dose unknown	1997		Yes	MH-3
		15JUL2015	20OCT2015	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxe	40 mg/d	14Jul2015	20Jul2015		
		15JUL2015	20OCT2015	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Stomach Protection	20 mg/d	07Jul2015	27Jul2015		
		15JUL2015	20OCT2015	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: Infection Prevention	1.5 g/d	15Jul2015	15Jul2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Infection Prevention	1.5 g/d	15Jul2015	15Jul2015		
		15JUL2015	20OCT2015	Dikaliumclorazepa t	CLORAZEPATE DIPOTASSIUM	PSYCHOLEPTICS	Other: preoperative	20 mg	20Oct2015	20Oct2015		
		15JUL2015	20OCT2015	Vitamin C	ASCORBIC ACID	OPHTHALMOLOGICA LS	Other: prophylaxis (AE no. 02)	2000 mg	22Dec2015	26Dec2015		AE-2
		15JUL2015	20OCT2015	Vitamin C	ASCORBIC ACID	VITAMINS	Other: prophylaxis (AE no. 02)	2000 mg	22Dec2015	26Dec2015		AE-2
		15JUL2015	20OCT2015	Vitamin C	ASCORBIC ACID	ALL OTHER THERAPEUTIC PRODUCTS	Other: prophylaxis (AE no. 02)	2000 mg	22Dec2015	26Dec2015		AE-2
		15JUL2015	20OCT2015	Vitamin C	ASCORBIC ACID	HOMEOPATHIC PREPARATION	Other: prophylaxis (AE no. 02)	2000 mg	22Dec2015	26Dec2015		AE-2
		15JUL2015	20OCT2015	Vitamin C	ASCORBIC ACID	ALL OTHER NON-THERAPEUTIC PRODUCTS	Other: prophylaxis (AE no. 02)	2000 mg	22Dec2015	26Dec2015		AE-2
		15JUL2015	20OCT2015	Vitamin C	ASCORBIC ACID	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: prophylaxis (AE no. 02)	2000 mg	22Dec2015	26Dec2015		AE-2
		15JUL2015	20OCT2015	Vitamin C	ASCORBIC ACID	OTHER DERMATOLOGICAL PREPARATIONS	Other: prophylaxis (AE no. 02)	2000 mg	22Dec2015	26Dec2015		AE-2
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	OPHTHALMOLOGICA LS	Other: cataract (AE no. 03)	1 drop 10 mg/ml	19Feb2016	26Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	VASOPROTECTIVES	Other: cataract (AE no. 03)	1 drop 10 mg/ml	19Feb2016	26Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	STOMATOLOGICAL PREPARATIONS	Other: cataract (AE no. 03)	1 drop 10 mg/ml	19Feb2016	26Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	OTOLOGICALS	Other: cataract (AE no. 03)	1 drop 10 mg/ml	19Feb2016	26Feb2016		AE-3

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: cataract (AE no. 03)	1 drop 10 mg/ml	19Feb2016	26Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: cataract (AE no. 03)	1 drop 10 mg/ml	19Feb2016	26Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: cataract (AE no. 03)	1 drop 10 mg/ml	19Feb2016	26Feb2016		AE-3
		15JUL2015	20OCT2015	Pregabalin	PREGABALIN	PSYCHOLEPTICS	Pain-other (AE no. 05)	50 mg	16May2016	09Feb2017		AE-5
		15JUL2015	20OCT2015	Pregabalin	PREGABALIN	ANTIEPILEPTICS	Pain-other (AE no. 05)	50 mg	16May2016	09Feb2017		AE-5
		15JUL2015	20OCT2015	Pregabalin	PREGABALIN	ANALGESICS	Pain-other (AE no. 05)	50 mg	16May2016	09Feb2017		AE-5
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	VASOPROTECTIVES	Other: cataract (AE no. 06)	3 drops 10 mg/ml	18May2016	25May2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	STOMATOLOGICAL PREPARATIONS	Other: cataract (AE no. 06)	3 drops 10 mg/ml	18May2016	25May2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	OTOLOGICALS	Other: cataract (AE no. 06)	3 drops 10 mg/ml	18May2016	25May2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: cataract (AE no. 06)	3 drops 10 mg/ml	18May2016	25May2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	OPHTHALMOLOGICA LS	Other: cataract (AE no. 06)	3 drops 10 mg/ml	18May2016	25May2016		AE-6

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: cataract (AE no. 06)	3 drops 10 mg/ml	18May2016	25May2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: cataract (AE no. 06)	3 drops 10 mg/ml	18May2016	25May2016		AE-6
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	6 mg	11Jul2016	11Jul2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	4.5 mg	26Jul2016	26Jul2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	6 mg	22Jul2016	22Jul2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	4.5 mg	06Aug2016	06Aug2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	6 mg	13Aug2016	13Aug2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	6 mg	20Aug2016	20Aug2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	6 mg	27Aug2016	27Aug2016		AE-5

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	6 mg	03Sep2016	03Sep2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	6 mg	10Sep2016	10Sep2016		AE-5
		15JUL2015	20OCT2015	Pyridostigmin	PYRIDOSTIGMINE	OTHER NERVOUS SYSTEM DRUGS	Other: Myasthenia gravis (AE no. 07)	60 mg	19Jan2017	08Feb2017		AE-7
		15JUL2015	20OCT2015	Pyridostigmin	PYRIDOSTIGMINE	OTHER NERVOUS SYSTEM DRUGS	Other: Myasthenia gravis (AE no. 07)	160 mg	06Mar2017	12May2017		AE-7
		15JUL2015	20OCT2015	Calciferol	VITAMIN D NOS	VITAMINS	Other: Myasthenia gravis (AE no. 07)	2000 IU	09Feb2017		Yes	AE-7
		15JUL2015	20OCT2015	Colecalciferol	COLECALCIFEROL	VITAMINS	Other: Myasthenia gravis (AE no. 07)	20000 IU per week	24Feb2017		Yes	AE-7
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	15Sep2016	16Sep2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	22Sep2016	23Sep2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	29Sep2016	30Sep2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	06Oct2016	07Oct2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	13Oct2016	14Oct2016		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	20Oct2016	21Oct2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	27Oct2016	28Oct2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	03Nov2016	04Nov2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	10Nov2016	11Nov2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	17Nov2016	18Nov2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	24Nov2016	25Nov2016		
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Myasthenia gravis (AE no. 07)	2.5 mg	21Oct2017	21Oct2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	2.5 mg	21Oct2017	21Oct2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	NASAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	2.5 mg	21Oct2017	21Oct2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OPHTHALMOLOGICA LS	Other: Myasthenia gravis (AE no. 07)	2.5 mg	21Oct2017	21Oct2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OTOLOGICALS	Other: Myasthenia gravis (AE no. 07)	2.5 mg	21Oct2017	21Oct2017		AE-7

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	2.5 mg	21Oct2017	21Oct2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	2.5 mg	21Oct2017	21Oct2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: Myasthenia gravis (AE no. 07)	2.5 mg	21Oct2017	21Oct2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	VASOPROTECTIVES	Other: Myasthenia gravis (AE no. 07)	2.5 mg	21Oct2017	21Oct2017		AE-7
		15JUL2015	20OCT2015	Havrix	HEPATITIS A VACCINE	VACCINES	Other: HepA vaccination	UNK	04Oct2018	04Oct2018		
		15JUL2015	20OCT2015	Shingrix 2	VARICELLA ZOSTER VACCINE	VACCINES	Other: Shingles vaccination	0.5 ml	08Jul2020	08Jul2020		
		15JUL2015	20OCT2015	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic drug (AE no. 11)	500 mg	12Dec2019	19Dec2019		AE-11
		15JUL2015	20OCT2015	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: antibiotic drug (AE no. 11)	500 mg	12Dec2019	19Dec2019		AE-11
		15JUL2015	20OCT2015	Bisohexal	BISOPROLOL FUMARATE	BETA BLOCKING AGENTS	Other: Tachycardy (MedHis no. 2)	2-5 mg/d	2012		Yes	MH-2
		15JUL2015	20OCT2015	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: prophylaxis	20 mg	21Oct2015	22Oct2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: cataract (AE no. 03)	4 drops 10 mg/ml	26Jan2016	02Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: cataract (AE no. 03)	4 drops 10 mg/ml	26Jan2016	02Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	OTOLOGICALS	Other: cataract (AE no. 03)	4 drops 10 mg/ml	26Jan2016	02Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	Other: cataract (AE no. 03)	4 drops 10 mg/ml	26Jan2016	02Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	STOMATOLOGICAL PREPARATIONS	Other: cataract (AE no. 03)	4 drops 10 mg/ml	26Jan2016	02Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	VASOPROTECTIVES	Other: cataract (AE no. 03)	4 drops 10 mg/ml	26Jan2016	02Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	OPHTHALMOLOGICALS	Other: cataract (AE no. 03)	4 drops 10 mg/ml	26Jan2016	02Feb2016		AE-3
		15JUL2015	20OCT2015	Enoxaparin	ENOXAPARIN	ANTITHROMBOTIC AGENTS	Other: deep vein thrombosis (AE no. 05)	160 mg sc.	16May2016	07Jul2016		AE-5
		15JUL2015	20OCT2015	Marcumar=Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis (AE no. 05)	9 mg	08Jul2016	08Jul2016		AE-5
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: cataract (AE no. 06)	1 drop 10 mg/ml	03Jun2016	10Jun2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: cataract (AE no. 06)	1 drop 10 mg/ml	03Jun2016	10Jun2016		AE-6

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	OPHTHALMOLOGICA LS	Other: cataract (AE no. 06)	1 drop 10 mg/ml	03Jun2016	10Jun2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: cataract (AE no. 06)	1 drop 10 mg/ml	03Jun2016	10Jun2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	OTOLOGICALS	Other: cataract (AE no. 06)	1 drop 10 mg/ml	03Jun2016	10Jun2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	STOMATOLOGICAL PREPARATIONS	Other: cataract (AE no. 06)	1 drop 10 mg/ml	03Jun2016	10Jun2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	VASOPROTECTIVES	Other: cataract (AE no. 06)	1 drop 10 mg/ml	03Jun2016	10Jun2016		AE-6
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	3 mg	12Jul2016	12Jul2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	3 mg	27Jul2016	29Jul2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	3 mg	31Jul2016	01Aug2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	3 mg	07Aug2016	08Aug2016		AE-5

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing? MH/AE	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	3 mg	14Aug2016	15Aug2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	3 mg	21Aug2016	22Aug2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	3 mg	28Aug2016	29Aug2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	3 mg	04Sep2016	05Sep2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	3 mg	11Sep2016	13Sep2016		AE-5
		15JUL2015	20OCT2015	Pyridostigmin	PYRIDOSTIGMINE	OTHER NERVOUS SYSTEM DRUGS	Other: Myasthenia gravis (AE no. 07)	180 mg	09Feb2017	05Mar2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	NASAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	40 mg	09Feb2017	23Feb2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OPHTHALMOLOGICA LS	Other: Myasthenia gravis (AE no. 07)	40 mg	09Feb2017	23Feb2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	VASOPROTECTIVES	Other: Myasthenia gravis (AE no. 07)	40 mg	09Feb2017	23Feb2017		AE-7

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: Myasthenia gravis (AE no. 07)	40 mg	09Feb2017	23Feb2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	40 mg	09Feb2017	23Feb2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OTOLOGICALS	Other: Myasthenia gravis (AE no. 07)	40 mg	09Feb2017	23Feb2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	40 mg	09Feb2017	23Feb2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Myasthenia gravis (AE no. 07)	40 mg	09Feb2017	23Feb2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	40 mg	09Feb2017	23Feb2017		AE-7
		15JUL2015	20OCT2015	Methotrexat	METHOTREXATE	ANTINEOPLASTIC AGENTS	Other: Myasthenia gravis (AE no. 07)	10 mg/week	24Feb2017	12May2017		AE-7
		15JUL2015	20OCT2015	Methotrexat	METHOTREXATE	IMMUNOSUPPRESSA NTS	Other: Myasthenia gravis (AE no. 07)	10 mg/week	24Feb2017	12May2017		AE-7
		15JUL2015	20OCT2015	Methotrexat	METHOTREXATE	OTHER GYNECOLOGICALS	Other: Myasthenia gravis (AE no. 07)	10 mg/week	24Feb2017	12May2017		AE-7

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: prophylaxis (AE no. 07)	UNK	24Feb2017	05Mar2017		AE-7
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	4.5 mg	17Sep2016	17Sep2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	4.5 mg	24Sep2016	24Sep2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	4.5 mg	01Oct2016	01Oct2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	4.5 mg	08Oct2016	08Oct2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	4.5 mg	15Oct2016	15Oct2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	4.5 mg	22Oct2016	22Oct2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	4.5 mg	29Oct2016	29Oct2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	4.5 mg	05Nov2016	05Nov2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	4.5 mg	12Nov2016	12Nov2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	4.5 mg	19Nov2016	19Nov2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	4.5 mg	26Nov2016	26Nov2016		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	VASOPROTECTIVES	Other: Myasthenia gravis (AE no. 07)	5 mg every 2 days	23Oct2017	13Jul2018		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	5 mg every 2 days	23Oct2017	13Jul2018		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: Myasthenia gravis (AE no. 07)	5 mg every 2 days	23Oct2017	13Jul2018		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OTOLOGICALS	Other: Myasthenia gravis (AE no. 07)	5 mg every 2 days	23Oct2017	13Jul2018		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	5 mg every 2 days	23Oct2017	13Jul2018		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OPHTHALMOLOGICA LS	Other: Myasthenia gravis (AE no. 07)	5 mg every 2 days	23Oct2017	13Jul2018		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	NASAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	5 mg every 2 days	23Oct2017	13Jul2018		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	5 mg every 2 days	23Oct2017	13Jul2018		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Myasthenia gravis (AE no. 07)	5 mg every 2 days	23Oct2017	13Jul2018		AE-7

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Myasthenia gravis (AE no. 07)	1 mg every second day	31Aug2019	01Apr2020		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	1 mg every second day	31Aug2019	01Apr2020		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	VASOPROTECTIVES	Other: Myasthenia gravis (AE no. 07)	1 mg every second day	31Aug2019	01Apr2020		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	1 mg every second day	31Aug2019	01Apr2020		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: Myasthenia gravis (AE no. 07)	1 mg every second day	31Aug2019	01Apr2020		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OTOLOGICALS	Other: Myasthenia gravis (AE no. 07)	1 mg every second day	31Aug2019	01Apr2020		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	1 mg every second day	31Aug2019	01Apr2020		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OPHTHALMOLOGICA LS	Other: Myasthenia gravis (AE no. 07)	1 mg every second day	31Aug2019	01Apr2020		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	NASAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	1 mg every second day	31Aug2019	01Apr2020		AE-7

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Influsplit Tetra	INFLUENZA VACCINE	VACCINES	Other: Influenza vaccination	0.5 ml	29Jan2020	29Jan2020		
		15JUL2015	20OCT2015	Metronidazol	METRONIDAZOLE	ANTIPROTOZOALS	Other: antibiotic drug (AE no. 12)	400 mg	04Sep2020	13Sep2020		AE-12
		15JUL2015	20OCT2015	Metronidazol	METRONIDAZOLE	STOMATOLOGICAL PREPARATIONS	Other: antibiotic drug (AE no. 12)	400 mg	04Sep2020	13Sep2020		AE-12
		15JUL2015	20OCT2015	Metronidazol	METRONIDAZOLE	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic drug (AE no. 12)	400 mg	04Sep2020	13Sep2020		AE-12
		15JUL2015	20OCT2015	Metronidazol	METRONIDAZOLE	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: antibiotic drug (AE no. 12)	400 mg	04Sep2020	13Sep2020		AE-12
		15JUL2015	20OCT2015	Metronidazol	METRONIDAZOLE	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: antibiotic drug (AE no. 12)	400 mg	04Sep2020	13Sep2020		AE-12
		15JUL2015	20OCT2015	potassium	POTASSIUM	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: prophylaxis hypokalemia	40 mmol/d	13Jul2015	20Jul2015		
		15JUL2015	20OCT2015	potassium	POTASSIUM	OPHTHALMOLOGICA LS	Other: prophylaxis hypokalemia	40 mmol/d	13Jul2015	20Jul2015		
		15JUL2015	20OCT2015	potassium	POTASSIUM	STOMATOLOGICAL PREPARATIONS	Other: prophylaxis hypokalemia	40 mmol/d	13Jul2015	20Jul2015		
		15JUL2015	20OCT2015	potassium	POTASSIUM	MINERAL SUPPLEMENTS	Other: prophylaxis hypokalemia	40 mmol/d	13Jul2015	20Jul2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	potassium	POTASSIUM	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: prophylaxis hypokalemia	40 mmol/d	13Jul2015	20Jul2015		
		15JUL2015	20OCT2015	potassium	POTASSIUM	HOMEOPATHIC PREPARATION	Other: prophylaxis hypokalemia	40 mmol/d	13Jul2015	20Jul2015		
		15JUL2015	20OCT2015	Dikaliumchlorazep at	CLORAZEPATE DIPOTASSIUM	PSYCHOLEPTICS	Other: preoperative	10 mg	19Oct2015	19Oct2015		
		15JUL2015	20OCT2015	ASS	ACETYLSALICYLIC ACID	STOMATOLOGICAL PREPARATIONS	Other: Prophylaxis	100 mg	26Oct2015		Yes	
		15JUL2015	20OCT2015	ASS	ACETYLSALICYLIC ACID	ANTITHROMBOTIC AGENTS	Other: Prophylaxis	100 mg	26Oct2015		Yes	
		15JUL2015	20OCT2015	ASS	ACETYLSALICYLIC ACID	ANALGESICS	Other: Prophylaxis	100 mg	26Oct2015		Yes	
		15JUL2015	20OCT2015	ASS	ACETYLSALICYLIC ACID	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: Prophylaxis	100 mg	26Oct2015		Yes	
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	OPHTHALMOLOGICA LS	Other: cataract (AE no. 03)	3 drops 10 mg/ml	03Feb2016	10Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	VASOPROTECTIVES	Other: cataract (AE no. 03)	3 drops 10 mg/ml	03Feb2016	10Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	STOMATOLOGICAL PREPARATIONS	Other: cataract (AE no. 03)	3 drops 10 mg/ml	03Feb2016	10Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	OTOLOGICALS	Other: cataract (AE no. 03)	3 drops 10 mg/ml	03Feb2016	10Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: cataract (AE no. 03)	3 drops 10 mg/ml	03Feb2016	10Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: cataract (AE no. 03)	3 drops 10 mg/ml	03Feb2016	10Feb2016		AE-3

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: cataract (AE no. 03)	3 drops 10 mg/ml	03Feb2016	10Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	VASOPROTECTIVES	Other: cataract (AE no. 06)	4 drops 10 mg/ml	10May2016	17May2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	STOMATOLOGICAL PREPARATIONS	Other: cataract (AE no. 06)	4 drops 10 mg/ml	10May2016	17May2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	OTOLOGICALS	Other: cataract (AE no. 06)	4 drops 10 mg/ml	10May2016	17May2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	Other: cataract (AE no. 06)	4 drops 10 mg/ml	10May2016	17May2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	OPHTHALMOLOGICALS	Other: cataract (AE no. 06)	4 drops 10 mg/ml	10May2016	17May2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: cataract (AE no. 06)	4 drops 10 mg/ml	10May2016	17May2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: cataract (AE no. 06)	4 drops 10 mg/ml	10May2016	17May2016		AE-6
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	6 mg	09Jul2016	09Jul2016		AE-5

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	9 mg	13Jul2016	13Jul2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	4.5 mg	30Jul2016	30Jul2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	4.5 mg	02Aug2016	02Aug2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	6 mg	09Aug2016	09Aug2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	4.5 mg	16Aug2016	16Aug2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	4.5 mg	23Aug2016	23Aug2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	4.5 mg	30Aug2016	30Aug2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	4.5 mg	06Sep2016	06Sep2016		AE-5
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	35 mg	24Feb2017	23Mar2017		AE-7

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Myasthenia gravis (AE no. 07)	35 mg	24Feb2017	23Mar2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OTOLOGICALS	Other: Myasthenia gravis (AE no. 07)	35 mg	24Feb2017	23Mar2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	35 mg	24Feb2017	23Mar2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	35 mg	24Feb2017	23Mar2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: Myasthenia gravis (AE no. 07)	35 mg	24Feb2017	23Mar2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	VASOPROTECTIVES	Other: Myasthenia gravis (AE no. 07)	35 mg	24Feb2017	23Mar2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OPHTHALMOLOGICA LS	Other: Myasthenia gravis (AE no. 07)	35 mg	24Feb2017	23Mar2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	NASAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	35 mg	24Feb2017	23Mar2017		AE-7
		15JUL2015	20OCT2015	Cortison	CORTISONE ACETATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Myasthenia gravis (AE no. 07)	40 mg	24Feb2017	24Feb2017		AE-7

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Cortison	CORTISONE ACETATE	HOMEOPATHIC PREPARATION	Other: Myasthenia gravis (AE no. 07)	40 mg	24Feb2017	24Feb2017		AE-7
		15JUL2015	20OCT2015	Cortison	CORTISONE ACETATE	OPHTHALMOLOGICA LS	Other: Myasthenia gravis (AE no. 07)	40 mg	24Feb2017	24Feb2017		AE-7
		15JUL2015	20OCT2015	Methotrexat	METHOTREXATE	IMMUNOSUPPRESSA NTS	Other: Myasthenia gravis (AE no. 07)	15 mg per week	13May2017	01Oct2020		AE-7
		15JUL2015	20OCT2015	Methotrexat	METHOTREXATE	ANTINEOPLASTIC AGENTS	Other: Myasthenia gravis (AE no. 07)	15 mg per week	13May2017	01Oct2020		AE-7
		15JUL2015	20OCT2015	Methotrexat	METHOTREXATE	OTHER GYNECOLOGICALS	Other: Myasthenia gravis (AE no. 07)	15 mg per week	13May2017	01Oct2020		AE-7
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	18Sep2016	20Sep2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	25Sep2016	27Sep2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	02Oct2016	04Oct2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	09Oct2016	11Oct2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	16Oct2016	18Oct2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	23Oct2016	25Oct2016		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUNON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	30Oct2016	01Nov2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUNON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	06Nov2016	08Nov2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUNON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	13Nov2016	15Nov2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUNON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	20Nov2016	22Nov2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUNON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	3 mg	27Nov2016	29Nov2016		
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Myasthenia gravis (AE no. 07)	2.5 mg every 2 days	15Jul2018	30Aug2019		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	2.5 mg every 2 days	15Jul2018	30Aug2019		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	NASAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	2.5 mg every 2 days	15Jul2018	30Aug2019		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OPHTHALMOLOGICA LS	Other: Myasthenia gravis (AE no. 07)	2.5 mg every 2 days	15Jul2018	30Aug2019		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OTOLOGICALS	Other: Myasthenia gravis (AE no. 07)	2.5 mg every 2 days	15Jul2018	30Aug2019		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	2.5 mg every 2 days	15Jul2018	30Aug2019		AE-7

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	2.5 mg every 2 days	15Jul2018	30Aug2019		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: Myasthenia gravis (AE no. 07)	2.5 mg every 2 days	15Jul2018	30Aug2019		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	VASOPROTECTIVES	Other: Myasthenia gravis (AE no. 07)	2.5 mg every 2 days	15Jul2018	30Aug2019		AE-7
		15JUL2015	20OCT2015	Methotrexat	METHOTREXATE	OTHER GYNECOLOGICALS	Other: Myasthenia gravis (AE no. 07)	10 mg per week	02Oct2020		Yes	AE-7
		15JUL2015	20OCT2015	Methotrexat	METHOTREXATE	IMMUNOSUPPRESSA NTS	Other: Myasthenia gravis (AE no. 07)	10 mg per week	02Oct2020		Yes	AE-7
		15JUL2015	20OCT2015	Methotrexat	METHOTREXATE	ANTINEOPLASTIC AGENTS	Other: Myasthenia gravis (AE no. 07)	10 mg per week	02Oct2020		Yes	AE-7
		15JUL2015	20OCT2015	Vaxigrip Tetra	INFLUENZA VACCINE	VACCINES	Other: Influenza vaccination	0.5 ml	02Oct2020	02Oct2020		
		15JUL2015	20OCT2015	Mono Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: prophylaxis	3000 IU	20Oct2015	21Oct2015		
		15JUL2015	20OCT2015	Wick medinait	VICKS MEDINAIT	COUGH AND COLD PREPARATIONS	Other: common cold (AE no. 02)	30 ml	22Dec2015	27Dec2015		AE-2
		15JUL2015	20OCT2015	Inflanefran Eye drops	/01062901/ PREDNISOLONE ACETATE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: cataract (AE no. 03)	2 drops 10 mg/ml	11Feb2016	18Feb2016		AE-3

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: cataract (AE no. 03)	2 drops 10 mg/ml	11Feb2016	18Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	OTOLOGICALS	Other: cataract (AE no. 03)	2 drops 10 mg/ml	11Feb2016	18Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	Other: cataract (AE no. 03)	2 drops 10 mg/ml	11Feb2016	18Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	STOMATOLOGICAL PREPARATIONS	Other: cataract (AE no. 03)	2 drops 10 mg/ml	11Feb2016	18Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	VASOPROTECTIVES	Other: cataract (AE no. 03)	2 drops 10 mg/ml	11Feb2016	18Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran Eye drops	PREDNISOLONE ACETATE	OPHTHALMOLOGICALS	Other: cataract (AE no. 03)	2 drops 10 mg/ml	11Feb2016	18Feb2016		AE-3
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: cataract (AE no. 06)	2 drops 10 mg/ml	26May2016	02Jun2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: cataract (AE no. 06)	2 drops 10 mg/ml	26May2016	02Jun2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	OPHTHALMOLOGICALS	Other: cataract (AE no. 06)	2 drops 10 mg/ml	26May2016	02Jun2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	OTOLOGICALS	Other: cataract (AE no. 06)	2 drops 10 mg/ml	26May2016	02Jun2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	Other: cataract (AE no. 06)	2 drops 10 mg/ml	26May2016	02Jun2016		AE-6

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	STOMATOLOGICAL PREPARATIONS	Other: cataract (AE no. 06)	2 drops 10 mg/ml	26May2016	02Jun2016		AE-6
		15JUL2015	20OCT2015	Inflanefran eye drops approximately Prednisolonacetat	PREDNISOLONE ACETATE	VASOPROTECTIVES	Other: cataract (AE no. 06)	2 drops 10 mg/ml	26May2016	02Jun2016		AE-6
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	4.5 mg	10Jul2016	10Jul2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	3 mg	14Jul2016	21Jul2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	3 mg	23Jul2016	25Jul2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	3 mg	03Aug2016	05Aug2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	3 mg	10Aug2016	12Aug2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	3 mg	17Aug2016	19Aug2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	3 mg	24Aug2016	26Aug2016		AE-5

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	3 mg	31Aug2016	02Sep2016		AE-5
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis (AE no. 05)	3 mg	07Sep2016	09Sep2016		AE-5
		15JUL2015	20OCT2015	Folic acid	FOLIC ACID	ANTIANEMIC PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	5 mg/week	24Feb2017		Yes	AE-7
		15JUL2015	20OCT2015	Folic acid	FOLIC ACID	DIAGNOSTIC AGENTS	Other: Myasthenia gravis (AE no. 07)	5 mg/week	24Feb2017		Yes	AE-7
		15JUL2015	20OCT2015	Folic acid	FOLIC ACID	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: Myasthenia gravis (AE no. 07)	5 mg/week	24Feb2017		Yes	AE-7
		15JUL2015	20OCT2015	Cortison	CORTISONE ACETATE	OPHTHALMOLOGICA LS	Other: Myasthenia gravis (AE no. 07)	30 mg	25Feb2017	04Mar2017		AE-7
		15JUL2015	20OCT2015	Cortison	CORTISONE ACETATE	HOMEOPATHIC PREPARATION	Other: Myasthenia gravis (AE no. 07)	30 mg	25Feb2017	04Mar2017		AE-7
		15JUL2015	20OCT2015	Cortison	CORTISONE ACETATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Myasthenia gravis (AE no. 07)	30 mg	25Feb2017	04Mar2017		AE-7
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	6 mg	14Sep2016	14Sep2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	6 mg	21Sep2016	21Sep2016		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	6 mg	28Sep2016	28Sep2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	6 mg	05Oct2016	05Oct2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	4.5 mg	12Oct2016	12Oct2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	4.5 mg	19Oct2016	19Oct2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	4.5 mg	26Oct2016	26Oct2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	4.5 mg	02Nov2016	02Nov2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	4.5 mg	09Nov2016	09Nov2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	4.5 mg	16Nov2016	16Nov2016		
		15JUL2015	20OCT2015	Phenprocoumon	PHENPROCOUMON	ANTITHROMBOTIC AGENTS	Other: Thrombo-prophyl axis	4.5 mg	23Nov2016	23Nov2016		
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	VASOPROTECTIVES	Other: Myasthenia gravis (AE no. 07)	30 mg	24Mar2017	14Apr2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	30 mg	24Mar2017	14Apr2017		AE-7

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: Myasthenia gravis (AE no. 07)	30 mg	24Mar2017	14Apr2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OTOLOGICALS	Other: Myasthenia gravis (AE no. 07)	30 mg	24Mar2017	14Apr2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	30 mg	24Mar2017	14Apr2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	OPHTHALMOLOGICA LS	Other: Myasthenia gravis (AE no. 07)	30 mg	24Mar2017	14Apr2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	NASAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	30 mg	24Mar2017	14Apr2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Myasthenia gravis (AE no. 07)	30 mg	24Mar2017	14Apr2017		AE-7
		15JUL2015	20OCT2015	Prednisolon	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Myasthenia gravis (AE no. 07)	30 mg	24Mar2017	14Apr2017		AE-7
		15JUL2015	20OCT2015	Afluria	INFLUENZA VACCINE	VACCINES	Other: Influenza vaccination	UNK	05Dec2017	05Dec2017		
		15JUL2015	20OCT2015	Prevenar 13 pneumococci polysaccharid-con jugate vaccine	PNEUMOCOCCAL VACCINE	VACCINES	Other: Vaccination	0.5 ml	20Mar2020	20Mar2020		
		15JUL2015	20OCT2015	Shingrix 1	VARICELLA ZOSTER VACCINE	VACCINES	Other: Shingles vaccination	0.5 ml	17Feb2020	17Feb2020		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
06/0613	SC	20JUL2015	-	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Stomach Protection	20 mg/d	20Jul2015	26Jul2015	
		20JUL2015	-	Mono Embolex 30	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis	d/3000 IU	20Jul2015	24Jul2015	
		20JUL2015	-	Cefroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: Infection prevention	1.5 g	20Jul2015	20Jul2015	
		20JUL2015	-	Cefroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Infection prevention	1.5 g	20Jul2015	20Jul2015	
		20JUL2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other	1800 mg/d	20Jul2015	26Jul2015	
		20JUL2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other	1800 mg/d	20Jul2015	26Jul2015	
		20JUL2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other	1800 mg/d	20Jul2015	26Jul2015	
		20JUL2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-other	1800 mg/d	20Jul2015	26Jul2015	
		20JUL2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-other	1800 mg/d	20Jul2015	26Jul2015	
06/0614	ND plus	18AUG2015	18NOV2015	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: antibiotics	1500 mg	18Aug2015	18Aug2015	
		18AUG2015	18NOV2015	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotics	1500 mg	18Aug2015	18Aug2015	
		18AUG2015	18NOV2015	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Prophylaxis (AE no. 05)	20 mg	22Feb2016	18Mar2016	AE-5
		18AUG2015	18NOV2015	Ringer solution	COMPOUND SODIUM CHLORIDE /06440701/	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: prophylaxis	480 ml	11Aug2016	14Aug2016	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0614	ND plus	18AUG2015	18NOV2015	Ringer solution	COMPOUND SODIUM CHLORIDE /06440701/	NASAL PREPARATIONS	Other: prophylaxis	480 ml	11Aug2016	14Aug2016		
		18AUG2015	18NOV2015	Ringer solution	COMPOUND SODIUM CHLORIDE /06440701/	OTHER DERMATOLOGICAL PREPARATIONS	Other: prophylaxis	480 ml	11Aug2016	14Aug2016		
		18AUG2015	18NOV2015	Tranxilium=Dikali umchlorazepat	CLORAZEPATE DIPOTASSIUM	PSYCHOLEPTICS	Other: sleeping	20 mg	10Aug2016	10Aug2016		
		18AUG2015	18NOV2015	Pantazol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Protection stomach	20 mg	15Aug2015	22Aug2015		
		18AUG2015	18NOV2015	Dikaliumchlorazep at	CLORAZEPATE DIPOTASSIUM	PSYCHOLEPTICS	Other: pre-medication for surgery	20 mg	18Aug2015	18Aug2015		
		18AUG2015	18NOV2015	Mono Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Prophylaxis	3000 IU	11Mar2016	11Mar2016		
		18AUG2015	18NOV2015	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: prophylaxis (AE no. 07)	20 mg	13Aug2016	20Sep2016		AE-7
		18AUG2015	18NOV2015	Midazolam	MIDAZOLAM	PSYCHOLEPTICS	Other: sleeping	7.5 mg	11Aug2016	11Aug2016		
		18AUG2015	18NOV2015	Meersalz Nasenspray	SODIUM CHLORIDE	ECTOPARASITICID ES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS	Other: Prophylaxis (AE no. 02)	as needed	18Dec2015	26Dec2015		AE-2
		18AUG2015	18NOV2015	Meersalz Nasenspray	SODIUM CHLORIDE	NASAL PREPARATIONS	Other: Prophylaxis (AE no. 02)	as needed	18Dec2015	26Dec2015		AE-2
		18AUG2015	18NOV2015	Meersalz Nasenspray	SODIUM CHLORIDE	COUGH AND COLD PREPARATIONS	Other: Prophylaxis (AE no. 02)	as needed	18Dec2015	26Dec2015		AE-2
		18AUG2015	18NOV2015	Meersalz Nasenspray	SODIUM CHLORIDE	OPHTHALMOLOGICA LS	Other: Prophylaxis (AE no. 02)	as needed	18Dec2015	26Dec2015		AE-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0614	ND plus	18AUG2015	18NOV2015	Meersalz Nasenspray	SODIUM CHLORIDE	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: Prophylaxis (AE no. 02)	as needed	18Dec2015	26Dec2015		AE-2
		18AUG2015	18NOV2015	Meersalz Nasenspray	SODIUM CHLORIDE	DRUGS FOR CONSTIPATION	Other: Prophylaxis (AE no. 02)	as needed	18Dec2015	26Dec2015		AE-2
		18AUG2015	18NOV2015	Meersalz Nasenspray	SODIUM CHLORIDE	STOMATOLOGICAL PREPARATIONS	Other: Prophylaxis (AE no. 02)	as needed	18Dec2015	26Dec2015		AE-2
		18AUG2015	18NOV2015	Meersalz Nasenspray	SODIUM CHLORIDE	MINERAL SUPPLEMENTS	Other: Prophylaxis (AE no. 02)	as needed	18Dec2015	26Dec2015		AE-2
		18AUG2015	18NOV2015	Meersalz Nasenspray	SODIUM CHLORIDE	OTOLOGICALS	Other: Prophylaxis (AE no. 02)	as needed	18Dec2015	26Dec2015		AE-2
		18AUG2015	18NOV2015	Meersalz Nasenspray	SODIUM CHLORIDE	HOMEOPATHIC PREPARATION	Other: Prophylaxis (AE no. 02)	as needed	18Dec2015	26Dec2015		AE-2
		18AUG2015	18NOV2015	Meersalz Nasenspray	SODIUM CHLORIDE	ALL OTHER NON-THERAPEUTIC PRODUCTS	Other: Prophylaxis (AE no. 02)	as needed	18Dec2015	26Dec2015		AE-2
		18AUG2015	18NOV2015	Meersalz Nasenspray	SODIUM CHLORIDE	MEDICATED DRESSINGS	Other: Prophylaxis (AE no. 02)	as needed	18Dec2015	26Dec2015		AE-2
		18AUG2015	18NOV2015	Meersalz Nasenspray	SODIUM CHLORIDE	PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	Other: Prophylaxis (AE no. 02)	as needed	18Dec2015	26Dec2015		AE-2
		18AUG2015	18NOV2015	Pantoprazol	PANTOPRAZOLE	DRUGS FOR ACID RELATED DISORDERS	Other: prophylaxis (AE no. 06)	40 mg	11Jul2016	11Jul2016		AE-6
		18AUG2015	18NOV2015	Ondansetron	SESQUIHYDRATE ONDANSETRON	ANTIEMETICS AND ANTINAUSEANTS	Other: nausea (AE no. 09)	4 mg	12Aug2016	12Aug2016		AE-9
		18AUG2015	18NOV2015	Monoembolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombosis prevention	0.3 ml	16Aug2015	22Aug2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0614	ND plus	18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 02)	as needed 400 mg	18Dec2015	26Dec2015		AE-2
		18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATO RY AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 02)	as needed 400 mg	18Dec2015	26Dec2015		AE-2
		18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 02)	as needed 400 mg	18Dec2015	26Dec2015		AE-2
		18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 02)	as needed 400 mg	18Dec2015	26Dec2015		AE-2
		18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 02)	as needed 400 mg	18Dec2015	26Dec2015		AE-2
		18AUG2015	18NOV2015	Mono Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Prophylaxis	3000 IU	11Aug2016	18Aug2016		
		18AUG2015	18NOV2015	Ondansetron	ONDANSETRON	ANTIEMETICS AND ANTINAUSEANTS	Other: nausea (AE no. 09)	8 mg	13Aug2016	13Aug2016		AE-9
06/0615	ND basic	25AUG2015	-	Mono Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Prophylaxis	0.3 ml	25Aug2015	28Aug2015		
		25AUG2015	-	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotics	1.5 g	25Aug2015	25Aug2015		
		25AUG2015	-	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: antibiotics	1.5 g	25Aug2015	25Aug2015		
		25AUG2015	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: prophylaxis	20 mg	25Aug2015	Sep2015		
		25AUG2015	-	Midazolam	MIDAZOLAM	PSYCHOLEPTICS	Other: Sedativa	7.5 mg	25Aug2015	25Aug2015		
06/0616		09NOV2015	-	Oxazepam	OXAZEPAM	PSYCHOLEPTICS	Other: sleeping	10 mg	07Nov2015	14Nov2015		
		09NOV2015	-	Movicol Beutel	OSMOTICALLY ACTING LAXATIVES (90062401001)	DRUGS FOR CONSTIPATION	Other: obstipation	1x	12Nov2015	Nov2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0616		09NOV2015	-	Castor oil	RICINUS COMMUNIS OIL	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	Other: obstipation	5 ml	13Nov2015	13Nov2015		
		09NOV2015	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Prophylaxis	20 mg	03Nov2015		Yes	
		09NOV2015	-	Baldrian	VALERIANA OFFICINALIS	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	Other: sleeping	20 mg	06Nov2015	06Nov2015		
		09NOV2015	-	Lactulose	LACTULOSE	BILE AND LIVER THERAPY	Other: obstipation	30 ml	09Nov2015	09Nov2015		
		09NOV2015	-	Lactulose	LACTULOSE	DRUGS FOR CONSTIPATION	Other: obstipation	30 ml	09Nov2015	09Nov2015		
		09NOV2015	-	Allopurinol	ALLOPURINOL	ANTIGOUT PREPARATIONS	Other: elevated uric acid	150 mg	Jan2016		Yes	
		09NOV2015	-	Vocado HCT	TRIBENZOR	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Other: Hypertonia (MedHis no. 01)	40/10/25 mg	Oct2015		Yes	MH-1
		09NOV2015	-	Dexamethason	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: against tissue swelling	12 mg	04Nov2015	07Nov2015		
		09NOV2015	-	Dexamethason	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Other: against tissue swelling	12 mg	04Nov2015	07Nov2015		
		09NOV2015	-	Dexamethason	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: against tissue swelling	12 mg	04Nov2015	07Nov2015		
		09NOV2015	-	Dexamethason	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Other: against tissue swelling	12 mg	04Nov2015	07Nov2015		
		09NOV2015	-	Dexamethason	DEXAMETHASONE	VASOPROTECTIVES	Other: against tissue swelling	12 mg	04Nov2015	07Nov2015		
		09NOV2015	-	Dexamethason	DEXAMETHASONE	OTOLOGICALS	Other: against tissue swelling	12 mg	04Nov2015	07Nov2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
06/0616		09NOV2015	-	Dexamethason	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: against tissue swelling	12 mg	04Nov2015	07Nov2015	
		09NOV2015	-	Dexamethason	DEXAMETHASONE	NASAL PREPARATIONS	Other: against tissue swelling	12 mg	04Nov2015	07Nov2015	
		09NOV2015	-	Dexamethason	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: against tissue swelling	12 mg	04Nov2015	07Nov2015	
		09NOV2015	-	Dexamethason	DEXAMETHASONE	OPHTHALMOLOGICA LS	Other: against tissue swelling	12 mg	04Nov2015	07Nov2015	
		09NOV2015	-	Dexamethason	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: against tissue swelling	12 mg	04Nov2015	07Nov2015	
		09NOV2015	-	Laxoberal	SODIUM PICOSULFATE	DRUGS FOR CONSTIPATION	Other: obstipation	12 gtt	09Nov2015	09Nov2015	
		09NOV2015	-	Magnesium	MAGNESIUM	MINERAL SUPPLEMENTS	Other: prophylaxis	80 mg	10Nov2015	12Nov2015	
		09NOV2015	-	Mono Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Prophylaxis	3000 IU	08Nov2015	14Nov2015	
		09NOV2015	-	Baldrian	VALERIANA OFFICINALIS	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	Other: sleeping	UNK	07Nov2015	07Nov2015	
		09NOV2015	-	Glycerol	GLYCEROL	DRUGS FOR CONSTIPATION	Other: obstipation	85 %	13Nov2015	13Nov2015	
		09NOV2015	-	Glycerol	GLYCEROL	STOMATOLOGICAL PREPARATIONS	Other: obstipation	85 %	13Nov2015	13Nov2015	
		09NOV2015	-	Glycerol	GLYCEROL	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: obstipation	85 %	13Nov2015	13Nov2015	
		09NOV2015	-	Glycerol	GLYCEROL	OTOLOGICALS	Other: obstipation	85 %	13Nov2015	13Nov2015	
		09NOV2015	-	Glycerol	GLYCEROL	COUGH AND COLD PREPARATIONS	Other: obstipation	85 %	13Nov2015	13Nov2015	
		09NOV2015	-	Glycerol	GLYCEROL	OPHTHALMOLOGICA LS	Other: obstipation	85 %	13Nov2015	13Nov2015	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
06/0616		09NOV2015	-	Glycerol	GLYCEROL	OTHER GYNECOLOGICALS	Other: obstipation	85 %	13Nov2015	13Nov2015	
		09NOV2015	-	Glycerol	GLYCEROL	OTHER DERMATOLOGICAL PREPARATIONS	Other: obstipation	85 %	13Nov2015	13Nov2015	
		09NOV2015	-	Glycerol	GLYCEROL	EMOLLIENTS AND PROTECTIVES	Other: obstipation	85 %	13Nov2015	13Nov2015	
06/0617	ND plus	22DEC2015	-	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Antibiotics	1.5 g	22Dec2015	22Dec2015	
		22DEC2015	-	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICALS	Other: Antibiotics	1.5 g	22Dec2015	22Dec2015	
		22DEC2015	-	Ondansetron	ONDANSETRON	ANTIEMETICS AND ANTINAUSEANTS	Other: Nausea prophylactic	16 mg	18Dec2015	22Dec2015	
		22DEC2015	-	NaCl 0.9 %	SODIUM CHLORIDE	DRUGS FOR CONSTIPATION	Other: Infusion	1000 ml	18Dec2015	22Dec2015	
		22DEC2015	-	NaCl 0.9 %	SODIUM CHLORIDE	STOMATOLOGICAL PREPARATIONS	Other: Infusion	1000 ml	18Dec2015	22Dec2015	
		22DEC2015	-	NaCl 0.9 %	SODIUM CHLORIDE	MINERAL SUPPLEMENTS	Other: Infusion	1000 ml	18Dec2015	22Dec2015	
		22DEC2015	-	NaCl 0.9 %	SODIUM CHLORIDE	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: Infusion	1000 ml	18Dec2015	22Dec2015	
		22DEC2015	-	NaCl 0.9 %	SODIUM CHLORIDE	OTOLOGICALS	Other: Infusion	1000 ml	18Dec2015	22Dec2015	
		22DEC2015	-	NaCl 0.9 %	SODIUM CHLORIDE	ALL OTHER NON-THERAPEUTIC PRODUCTS	Other: Infusion	1000 ml	18Dec2015	22Dec2015	
		22DEC2015	-	NaCl 0.9 %	SODIUM CHLORIDE	HOMEOPATHIC PREPARATION	Other: Infusion	1000 ml	18Dec2015	22Dec2015	
		22DEC2015	-	NaCl 0.9 %	SODIUM CHLORIDE	NASAL PREPARATIONS	Other: Infusion	1000 ml	18Dec2015	22Dec2015	
		22DEC2015	-	NaCl 0.9 %	SODIUM CHLORIDE	ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS	Other: Infusion	1000 ml	18Dec2015	22Dec2015	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
06/0617	ND plus	22DEC2015	-	NaCl 0.9 %	SODIUM CHLORIDE	OPHTHALMOLOGICA LS	Other: Infusion	1000 ml	18Dec2015	22Dec2015	
		22DEC2015	-	NaCl 0.9 %	SODIUM CHLORIDE	COUGH AND COLD PREPARATIONS	Other: Infusion	1000 ml	18Dec2015	22Dec2015	
		22DEC2015	-	NaCl 0.9 %	SODIUM CHLORIDE	MEDICATED DRESSINGS	Other: Infusion	1000 ml	18Dec2015	22Dec2015	
		22DEC2015	-	NaCl 0.9 %	SODIUM CHLORIDE	PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	Other: Infusion	1000 ml	18Dec2015	22Dec2015	
		22DEC2015	-	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: against tissue swelling	16 mg	18Dec2015	18Dec2015	
		22DEC2015	-	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	Other: against tissue swelling	16 mg	18Dec2015	18Dec2015	
		22DEC2015	-	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: against tissue swelling	16 mg	18Dec2015	18Dec2015	
		22DEC2015	-	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	Other: against tissue swelling	16 mg	18Dec2015	18Dec2015	
		22DEC2015	-	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	Other: against tissue swelling	16 mg	18Dec2015	18Dec2015	
		22DEC2015	-	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Other: against tissue swelling	16 mg	18Dec2015	18Dec2015	
		22DEC2015	-	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: against tissue swelling	16 mg	18Dec2015	18Dec2015	
		22DEC2015	-	Fortecortin	DEXAMETHASONE	OTOLOGICALS	Other: against tissue swelling	16 mg	18Dec2015	18Dec2015	
		22DEC2015	-	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: against tissue swelling	16 mg	18Dec2015	18Dec2015	
		22DEC2015	-	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: against tissue swelling	16 mg	18Dec2015	18Dec2015	
		22DEC2015	-	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Other: against tissue swelling	16 mg	18Dec2015	18Dec2015	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0617	ND plus	22DEC2015	-	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Prophylaxis	40 mg	18Dec2015	28Dec2015		
06/0618		18JAN2016	-	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotics	1.5 g	18Jan2016	18Jan2016		
		18JAN2016	-	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: antibiotics	1.5 g	18Jan2016	18Jan2016		
06/0619	ND basic	23FEB2016	10MAY2016	Ramipril	RAMIPRIL	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Other: Hypertension (MedHis no. 01)	2.5 mg	2013	Dec2017		MH-1
		23FEB2016	10MAY2016	Midazolam	MIDAZOLAM	PSYCHOLEPTICS	Other: sedativa	7.5 mg	10May2016	10May2016		
		23FEB2016	10MAY2016	Lercamidipin	LERCANIDIPINE	CALCIUM CHANNEL BLOCKERS	Other: Hypertonie (MedHis no. 01)	10 mg	29May2017	Dec2017		MH-1
		23FEB2016	10MAY2016	Enalaprilmaleat / Lercanidipinhydro chlorid	ZANERIL	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Other: Hypertonie (MedHis no. 01)	20 mg/20 mg	Dec2017	Jul2019		MH-1
		23FEB2016	10MAY2016	Tianeptin Natrium	TIANEPTINE SODIUM	PSYCHOANALEPTIC S	Other: Depression (AE no. 08)	12.5 mg	Apr2018	Apr2018		AE-8
		23FEB2016	10MAY2016	Bisoprolol	BISOPROLOL	BETA BLOCKING AGENTS	Other: Hypertonie (MedHis no. 01)	2.5 mg	Feb2019		Yes	MH-1
		23FEB2016	10MAY2016	Cefazolin	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Erysipelas (AE no. 09)	UNK	24Aug2019	03Sep2019		AE-9
		23FEB2016	10MAY2016	Enalapril / Lercanidipin	ENALAPRIL W/LERCANIDIPINE	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Other: Hypertonie (MedHis no. 01)	20 mg / 20 mg	Jan2021		Yes	MH-1
		23FEB2016	10MAY2016	Comirnaty	OTHER VIRAL VACCINES (90125501001)	VACCINES	Other: COVID 19 vaccination	UNK	28Mar2021	28Mar2021		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0619	ND basic	23FEB2016	10MAY2016	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: Antibiotics	1.5 g	23Feb2016	23Feb2016		
		23FEB2016	10MAY2016	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Antibiotics	1.5 g	23Feb2016	23Feb2016		
		23FEB2016	10MAY2016	Cefuroxim	CEFUROXIME	OPHTHALMOLOGICA LS	Other: Antibiotics (AE no. 06)	UNK	Jan2017	Jan2017		AE-6
		23FEB2016	10MAY2016	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Antibiotics (AE no. 06)	UNK	Jan2017	Jan2017		AE-6
		23FEB2016	10MAY2016	Enalaprilmaleat	ENALAPRIL MALEATE	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Other: Hypertonie (MedHis no. 01)	10 mg as needed	Mar2018	Sep2018		MH-1
		23FEB2016	10MAY2016	Laif 900 Johanniskraut	HYPERICUM PERFORATUM	HOMEOPATHIC PREPARATION	Other: Depression (AE no. 08)	900 mg	25Jun2017	Apr2018		AE-8
		23FEB2016	10MAY2016	Laif 900 Johanniskraut	HYPERICUM PERFORATUM	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	Other: Depression (AE no. 08)	900 mg	25Jun2017	Apr2018		AE-8
		23FEB2016	10MAY2016	Atorvastatin	ATORVASTATIN	LIPID MODIFYING AGENTS	Other: prophylaxe	20 mg	Jan2021		Yes	
		23FEB2016	10MAY2016	Mucosolvan	AMBROXOL HYDROCHLORIDE	COUGH AND COLD PREPARATIONS	Other: Cough - Corona Infection (AE no. 11)	UNK	Sep2020	Oct2020		AE-11
		23FEB2016	10MAY2016	Mucosolvan	AMBROXOL HYDROCHLORIDE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: Cough - Corona Infection (AE no. 11)	UNK	Sep2020	Oct2020		AE-11
		23FEB2016	10MAY2016	Mucosolvan	AMBROXOL HYDROCHLORIDE	THROAT PREPARATIONS	Other: Cough - Corona Infection (AE no. 11)	UNK	Sep2020	Oct2020		AE-11

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0619	ND basic	23FEB2016	10MAY2016	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: prophylaxis	20 mg	22Feb2016	28Feb2016		
		23FEB2016	10MAY2016	Vit D3 Vigantoletten	COLECALCIFEROL	VITAMINS	Other: Prophylaxis	1000 IU	05Apr2016		Yes	
		23FEB2016	10MAY2016	Clavulanic acid amoxicillin	AMOXI-CLAVULANI CO	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Antibiotics (AE no. 06)	UNK	Jan2017	Jan2017		AE-6
		23FEB2016	10MAY2016	Tamsulosin	TAMSULOSIN	UROLOGICALS	Other: Prostata-Hyperp lasie (AE no. 10)	0.4 mg	Jan2021		Yes	AE-10
		23FEB2016	10MAY2016	Mono Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: prophylaxis	0.3 mg	23Feb2016	23Feb2016		
		23FEB2016	10MAY2016	Lora ADGC	LORATADINE	ANTIHIISTAMINES FOR SYSTEMIC USE	Other: Antiallergika (AE no. 02)	10 mg	12Apr2016	23Apr2016		AE-2
		23FEB2016	10MAY2016	Quetiapin	QUETIAPINE FUMARATE	PSYCHOLEPTICS	Other: Depression Insomnia (AE no. 08)	25 mg as needed	07Apr2018	Sep2018		AE-8
		23FEB2016	10MAY2016	Penicillin	BETA-LACTAM ANTIBACTERIALS, PENICILLINS (90028401001)	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Erysipelas (AE no. 09)	UNK	Aug2019	Aug2019		AE-9
		23FEB2016	10MAY2016	Comirnaty	OTHER VIRAL VACCINES (90125501001)	VACCINES	Other: COVID 19 vaccination	UNK	07Mar2021	07Mar2021		
06/0620	SC	24FEB2016	-	Midazolam	MIDAZOLAM	PSYCHOLEPTICS	Other: Sedativa	7.5 mg	24Feb2016	24Feb2016		
		24FEB2016	-	Volon Triamcinolonaceto nid	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICA LS	Other: hay fever (AE no. 01)	40 mg	27May2016	27May2016		AE-1
		24FEB2016	-	Volon Triamcinolonaceto nid	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: hay fever (AE no. 01)	40 mg	27May2016	27May2016		AE-1
		24FEB2016	-	Volon Triamcinolonaceto nid	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Other: hay fever (AE no. 01)	40 mg	27May2016	27May2016		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0620	SC	24FEB2016	-	Volon Triamcinolonaceto nid	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Other: hay fever (AE no. 01)	40 mg	27May2016	27May2016		AE-1
		24FEB2016	-	Volon Triamcinolonaceto nid	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Other: hay fever (AE no. 01)	40 mg	27May2016	27May2016		AE-1
		24FEB2016	-	Volon Triamcinolonaceto nid	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: hay fever (AE no. 01)	40 mg	27May2016	27May2016		AE-1
		24FEB2016	-	Volon Triamcinolonaceto nid	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS / DERMATOLOGICAL PREPARATIONS	Other: hay fever (AE no. 01)	40 mg	27May2016	27May2016		AE-1
		24FEB2016	-	Diclofenac	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Other: headache (AE no. 03)	75 mg	Feb2018	Feb2018		AE-3
		24FEB2016	-	Diclofenac	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: headache (AE no. 03)	75 mg	Feb2018	Feb2018		AE-3
		24FEB2016	-	Diclofenac	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: headache (AE no. 03)	75 mg	Feb2018	Feb2018		AE-3
		24FEB2016	-	Diclofenac	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Other: headache (AE no. 03)	75 mg	Feb2018	Feb2018		AE-3
		24FEB2016	-	Diclofenac	DICLOFENAC	THROAT PREPARATIONS	Other: headache (AE no. 03)	75 mg	Feb2018	Feb2018		AE-3
		24FEB2016	-	Diclofenac	DICLOFENAC	OPHTHALMOLOGICA LS	Other: headache (AE no. 03)	75 mg	Feb2018	Feb2018		AE-3
		24FEB2016	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: prophylaxis	20 mg	25Feb2016	07Mar2016		
		24FEB2016	-	Loratadin	LORATADINE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: Hay fever (AE no. 01)	10 mg	20May2016	27May2018		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0620	SC	24FEB2016	-	Triamcinolon - acetamid	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICA LS	Other: Hay fever (AE no. 07)	40 mg	May2020	May2020		AE-7
		24FEB2016	-	Triamcinolon - acetamid	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: Hay fever (AE no. 07)	40 mg	May2020	May2020		AE-7
		24FEB2016	-	Triamcinolon - acetamid	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Other: Hay fever (AE no. 07)	40 mg	May2020	May2020		AE-7
		24FEB2016	-	Triamcinolon - acetamid	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Other: Hay fever (AE no. 07)	40 mg	May2020	May2020		AE-7
		24FEB2016	-	Triamcinolon - acetamid	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Other: Hay fever (AE no. 07)	40 mg	May2020	May2020		AE-7
		24FEB2016	-	Triamcinolon - acetamid	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Hay fever (AE no. 07)	40 mg	May2020	May2020		AE-7
		24FEB2016	-	Triamcinolon - acetamid	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Hay fever (AE no. 07)	40 mg	May2020	May2020		AE-7
		24FEB2016	-	Mono Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: prophylaxis	3000 IU	24Feb2016	24Feb2016		
		24FEB2016	-	Immunoglobulin human anti-tetanus	IMMUNOGLOBULIN HUMAN	IMMUNE SERA AND	Other: Prophylaxe	1 ml	09Oct2020	09Oct2020		
		24FEB2016	-	Cefuroxim	ANTI-TETANUS CEFUROXIME	IMMUNOGLOBULINS OPHTHALMOLOGICA LS	Other: Antibiotics	1.5 g	24Feb2016	24Feb2016		
		24FEB2016	-	Cefuroxim	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Antibiotics	1.5 g	24Feb2016	24Feb2016		
07/0701	ND plus	06NOV2014	20JAN2015	Fragmin 2500 IE	DALTEPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Prophylaxis	1 x/d	05Nov2014	12Nov2014		
		06NOV2014	20JAN2015	Basocef	CEFAZOLIN SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: peri-OP Antibiotics	2 g/iv. 1x/peri-OP	06Nov2014	06Nov2014		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
07/0702	SC	20JAN2015	-	Basocef i.v. Antibiotika	CEFAZOLIN SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Post-operative Antibiosis	once 2 g/i.v. (routine)	20Jan2015	20Jan2015		
		20JAN2015	-	Fragmin 2500 IE	DALTEPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: prophylaxis	1 x/d	19Jan2015	26Jan2015		
		20JAN2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 02)	2 x 400 mg	03Sep2017	13Sep2017		AE-2
		20JAN2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 02)	2 x 400 mg	03Sep2017	13Sep2017		AE-2
		20JAN2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 02)	2 x 400 mg	03Sep2017	13Sep2017		AE-2
		20JAN2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 02)	2 x 400 mg	03Sep2017	13Sep2017		AE-2
		20JAN2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 02)	2 x 400 mg	03Sep2017	13Sep2017		AE-2
		20JAN2015	-	Kalinor 75 mg (Potassium)	POTASSIUM	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: Hypokalemia (AE no. 03)	1 x/d	19Jan2015	19Jan2015		AE-3
		20JAN2015	-	Kalinor 75 mg (Potassium)	POTASSIUM	STOMATOLOGICAL PREPARATIONS	Other: Hypokalemia (AE no. 03)	1 x/d	19Jan2015	19Jan2015		AE-3
		20JAN2015	-	Kalinor 75 mg (Potassium)	POTASSIUM	MINERAL SUPPLEMENTS	Other: Hypokalemia (AE no. 03)	1 x/d	19Jan2015	19Jan2015		AE-3
		20JAN2015	-	Kalinor 75 mg (Potassium)	POTASSIUM	HOMEOPATHIC PREPARATION	Other: Hypokalemia (AE no. 03)	1 x/d	19Jan2015	19Jan2015		AE-3
		20JAN2015	-	Kalinor 75 mg (Potassium)	POTASSIUM	OPHTHALMOLOGICA LS	Other: Hypokalemia (AE no. 03)	1 x/d	19Jan2015	19Jan2015		AE-3
		20JAN2015	-	Kalinor 75 mg (Potassium)	POTASSIUM	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: Hypokalemia (AE no. 03)	1 x/d	19Jan2015	19Jan2015		AE-3

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
07/0702	SC	20JAN2015	-	Cetirizin 10 mg	CETIRIZINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Other: Antiallergic Drug	1 x/d	19Jan2015	19Jan2015		
		20JAN2015	-	Cetirizin 10 mg	CETIRIZINE HYDROCHLORIDE	ANTIHIISTAMINES FOR SYSTEMIC USE	Other: Antiallergic Drug	1 x/d	19Jan2015	19Jan2015		
		20JAN2015	-	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Stomach prophylaxis	20 mg 1xd	13Jan2015		Yes	
		20JAN2015	-	Mirta TAD	MIRTAZAPINE	PSYCHOANALEPTIC S	Other: Antidepressant (AE no. 01)	30 mg 0-0-1/d	14Jun2015		Yes	AE-1
		20JAN2015	-	Fenistil ukn	DIMETINDENE MALEATE	ANTIHIISTAMINES FOR SYSTEMIC USE	Other: Antiallergic Drug (AE no. 04)	1 x/d	22Jan2015	22Jan2015		AE-4
		20JAN2015	-	Fenistil ukn	DIMETINDENE MALEATE	ANTIIPRURITICS, INCL. ANTIHIISTAMINES, ANESTHETICS, ETC.	Other: Antiallergic Drug (AE no. 04)	1 x/d	22Jan2015	22Jan2015		AE-4
07/0703	ND plus	03MAR2015	19MAY2015	Basocef -perioperativ-	CEFAZOLIN SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: perioperative antibioses	2 g/iv.	03Mar2015	03Mar2015		
		03MAR2015	19MAY2015	Viani ukn	SERETIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: asthma (allergic) (AE no. 02)	2 x/d	Sep2015	Nov2017		AE-2
		03MAR2015	19MAY2015	Ibuprofen 400 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: tooth-pain (AE no. 01)	0-2-0/d	18Jun2015	18Jun2015		AE-1
		03MAR2015	19MAY2015	Ibuprofen 400 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Other: tooth-pain (AE no. 01)	0-2-0/d	18Jun2015	18Jun2015		AE-1
		03MAR2015	19MAY2015	Ibuprofen 400 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: tooth-pain (AE no. 01)	0-2-0/d	18Jun2015	18Jun2015		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
07/0703	ND plus	03MAR2015	19MAY2015	Ibuprofen 400 mg	IBUPROFEN	THROAT PREPARATIONS	Other: tooth-pain (AE no. 01)	0-2-0/d	18Jun2015	18Jun2015		AE-1
		03MAR2015	19MAY2015	Ibuprofen 400 mg	IBUPROFEN	CARDIAC THERAPY	Other: tooth-pain (AE no. 01)	0-2-0/d	18Jun2015	18Jun2015		AE-1
07/0704	ND basic	16JUL2015	08OCT2015	Fragmin 2500 IE	DALTEPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Prophylaxis	1 x/d	15Jul2015	21Jul2015		
		16JUL2015	08OCT2015	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: prophylaxis	20 mg	08Oct2015	10Oct2015		
		16JUL2015	08OCT2015	Zofran 8 mg	ONDANSETRON	ANTIEMETICS AND ANTINAUSEANTS	Other: Vomiting (AE no. 01 02)	1x	16Jul2015	16Jul2015		
		16JUL2015	08OCT2015	Fragmin	DALTEPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: prophylaxis	2500 IE	08Oct2015	10Oct2015		
07/0705		13AUG2015	-	SEROQUEL	QUETIAPINE FUMARATE	PSYCHOLEPTICS	Other: Sleep disorder (MedHis no. 01)	50 mg	01Jul2014		Yes	MH-1
		13AUG2015	-	Omeprazol	OMEPRAZOLE	DRUGS FOR ACID RELATED DISORDERS	Other: Gastritis (MedHis no. 02)	20 mg	Jan2010		Yes	MH-2
		13AUG2015	-	Basocef	CEFAZOLIN SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: intra op antibiotic	1 g./iv.	13Aug2015	15Aug2015		
07/0706	SC	01DEC2015	-	Escitalopram	ESCITALOPRAM	PSYCHOANALEPTIC S	Other: Depression (MedHis no. 02)	10 mg/d	1996		Yes	MH-2
		01DEC2015	-	Mirtazapin	MIRTAZAPINE	PSYCHOANALEPTIC S	Other: Depression (MedHis no. 02)	15 mg/d	1996		Yes	MH-2
		01DEC2015	-	Pantozol 20 mg (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: prophylaxis	1-0-0	24Nov2015	28Nov2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
07/0706	SC	01DEC2015	-	Bisoprolol	BISOPROLOL	BETA BLOCKING AGENTS	Other: Hypertension (MedHis no. 03)	5 mg/d	UNK		Yes	MH-3
		01DEC2015	-	Pantozol 40 mg (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: prophylaxis	1-0-0	29Nov2015	03Dec2015		
		01DEC2015	-	Fragmin 2500 IE	DALTEPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: prophylaxis	1 x / d	24Nov2015	04Dec2015		
07/0707		-	-	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: prophylaxis for ulcer, anti-acid	20 mg 1x/d	14Feb2016		Yes	
08/0801	SC	03NOV2014	-	Tavor-Expidet (Lorazepam)	LORAZEPAM	ANTIEPILEPTICS	Other: anxiety, given before operation	1 mg	04May2015	04May2015		
		03NOV2014	-	Tavor-Expidet (Lorazepam)	LORAZEPAM	PSYCHOLEPTICS	Other: anxiety, given before operation	1 mg	04May2015	04May2015		
		03NOV2014	-	Zopiclon	ZOPICLONE	PSYCHOLEPTICS	Other: Insomnia (MedHis no. 04)	7.5 mg	01Jan2000		Yes	MH-4
		03NOV2014	-	Cefazolin	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Infection prophylaxis	2 gr	03Nov2014	03Nov2014		
		03NOV2014	-	Tavor (Lorazepam)	LORAZEPAM	ANTIEPILEPTICS	Other: Anxiety pre-operative	1 mg	03Nov2014	03Nov2014		
		03NOV2014	-	Tavor (Lorazepam)	LORAZEPAM	PSYCHOLEPTICS	Other: Anxiety pre-operative	1 mg	03Nov2014	03Nov2014		
		03NOV2014	-	Verapamil	VERAPAMIL	ANALGESICS	Other: Hypertonus (MedHis no. 02)	240 mg	01Jan2000		Yes	MH-2
		03NOV2014	-	Verapamil	VERAPAMIL	CALCIUM CHANNEL BLOCKERS	Other: Hypertonus (MedHis no. 02)	240 mg	01Jan2000		Yes	MH-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0801	SC	03NOV2014	-	Candesartan	CANDESARTAN	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Other: Hypertonus (MedHis no. 02)	8 mg	01Jan2000		Yes	MH-2
		03NOV2014	-	Doxepin	DOXEPIN	ANTIPRURITICS, INCL. ANTIHIISTAMINES, ANESTHETICS, ETC.	Other: Depression (MedHis no. 03)	50 mg	01Jan2012		Yes	MH-3
		03NOV2014	-	Doxepin	DOXEPIN	PSYCHOANALEPTIC S	Other: Depression (MedHis no. 03)	50 mg	01Jan2012		Yes	MH-3
		03NOV2014	-	Doxepin	DOXEPIN	PSYCHOLEPTICS	Other: Depression (MedHis no. 03)	50 mg	01Jan2012		Yes	MH-3
		03NOV2014	-	Berotec	FENOTEROL HYDROBROMIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: Asthma (MedHis no. 03)	100 ugr	07Jan2014		Yes	MH-3
		03NOV2014	-	Berotec	FENOTEROL HYDROBROMIDE	OTHER GYNECOLOGICALS	Other: Asthma (MedHis no. 03)	100 ugr	07Jan2014		Yes	MH-3
		03NOV2014	-	Mono-Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis	3000 IE	02Nov2014	05Nov2014		
08/0802	ND plus	27NOV2014	04MAR2015	Mono Embolex 3000	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis after lumbar surgery	3000 IE	27Nov2014	30Nov2014		
		27NOV2014	04MAR2015	Metoprolol	METOPROLOL	BETA BLOCKING AGENTS	Other: Migrane prophylaxis (AE no. 01, MedHis no. 02)	100 mg	01Oct2015	25Jan2017		AE-1
		27NOV2014	04MAR2015	Topiramate	TOPIRAMATE	ANALGESICS	Other: Migrane (AE no. 07)	50 mg	26Jan2017	Apr2019		AE-7
		27NOV2014	04MAR2015	Topiramate	TOPIRAMATE	ANTIEPILEPTICS	Other: Migrane (AE no. 07)	50 mg	26Jan2017	Apr2019		AE-7

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0802	ND plus	27NOV2014	04MAR2015	Pantozol (Pantoprazol)	PANTOPRAZOLE	DRUGS FOR ACID RELATED	Other:	40 mg	15Sep2014	05Dec2014		
		27NOV2014	04MAR2015	Rizatriptan	SODIUM SESQUIHYDRATE RIZATRIPTAN	DISORDERS ANALGESICS	gastritis prophylaxis Pain-other (AE no. 01, MedHis no. 02)	10 mg, once a month	01Oct2015		Yes	AE-1
		27NOV2014	04MAR2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Other: Migrane (AE no. 01)	800 mg	15May2015	15May2015		AE-1
		27NOV2014	04MAR2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Other: Migrane (AE no. 01)	800 mg	15May2015	15May2015		AE-1
		27NOV2014	04MAR2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: Migrane (AE no. 01)	800 mg	15May2015	15May2015		AE-1
		27NOV2014	04MAR2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Other: Migrane (AE no. 01)	800 mg	15May2015	15May2015		AE-1
		27NOV2014	04MAR2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: Migrane (AE no. 01)	800 mg	15May2015	15May2015		AE-1
		27NOV2014	04MAR2015	Xylocain	LIDOCAINE	ANESTHETICS	Pain-other (AE no. 03)	20 mg	07Dec2015	07Dec2015		AE-3
		27NOV2014	04MAR2015	Xylocain	LIDOCAINE	ANTIPRURITICS, INCL. ANTI HISTAMINES, ANESTHETICS, ETC.	Pain-other (AE no. 03)	20 mg	07Dec2015	07Dec2015		AE-3
		27NOV2014	04MAR2015	Xylocain	LIDOCAINE	UROLOGICALS	Pain-other (AE no. 03)	20 mg	07Dec2015	07Dec2015		AE-3
		27NOV2014	04MAR2015	Xylocain	LIDOCAINE	THROAT PREPARATIONS	Pain-other (AE no. 03)	20 mg	07Dec2015	07Dec2015		AE-3
		27NOV2014	04MAR2015	Xylocain	LIDOCAINE	OPHTHALMOLOGICA LS	Pain-other (AE no. 03)	20 mg	07Dec2015	07Dec2015		AE-3
		27NOV2014	04MAR2015	Xylocain	LIDOCAINE	VASOPROTECTIVES	Pain-other (AE no. 03)	20 mg	07Dec2015	07Dec2015		AE-3
		27NOV2014	04MAR2015	Xylocain	LIDOCAINE	CARDIAC THERAPY	Pain-other (AE no. 03)	20 mg	07Dec2015	07Dec2015		AE-3
		27NOV2014	04MAR2015	Xylocain	LIDOCAINE	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 03)	20 mg	07Dec2015	07Dec2015		AE-3

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0802	ND plus	27NOV2014	04MAR2015	Xylocain	LIDOCAINE	OTOLOGICALS	Pain-other (AE no. 03)	20 mg	07Dec2015	07Dec2015		AE-3
		27NOV2014	04MAR2015	Cefazolin	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: infection prophylaxis given for lumbar disc operation	2 gr	27Nov2014	27Nov2014		
		27NOV2014	04MAR2015	Imigran nasal (sumatriptan)	SUMATRIPTAN	ANALGESICS	Other: Migrane (AE no. 01)	10 mg	15May2015	15May2015		AE-1
		27NOV2014	04MAR2015	Prednisolon	PREDNISOLONE	OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	Pain-other (AE no. 03)	10 mg	07Dec2015	07Dec2015		AE-3
		27NOV2014	04MAR2015	Prednisolon	PREDNISOLONE	OTOLOGICALS	Pain-other (AE no. 03)	10 mg	07Dec2015	07Dec2015		AE-3
		27NOV2014	04MAR2015	Prednisolon	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	Pain-other (AE no. 03)	10 mg	07Dec2015	07Dec2015		AE-3
		27NOV2014	04MAR2015	Prednisolon	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 03)	10 mg	07Dec2015	07Dec2015		AE-3
		27NOV2014	04MAR2015	Prednisolon	PREDNISOLONE	VASOPROTECTIVES	Pain-other (AE no. 03)	10 mg	07Dec2015	07Dec2015		AE-3
		27NOV2014	04MAR2015	Prednisolon	PREDNISOLONE	OPHTHALMOLOGICALS	Pain-other (AE no. 03)	10 mg	07Dec2015	07Dec2015		AE-3
		27NOV2014	04MAR2015	Prednisolon	PREDNISOLONE	NASAL PREPARATIONS	Pain-other (AE no. 03)	10 mg	07Dec2015	07Dec2015		AE-3
		27NOV2014	04MAR2015	Prednisolon	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 03)	10 mg	07Dec2015	07Dec2015		AE-3
		27NOV2014	04MAR2015	Prednisolon	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 03)	10 mg	07Dec2015	07Dec2015		AE-3

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
08/0803	ND basic	25FEB2015	16JUN2015	Keltican forte (folic acid, uridine, vitamin B12)	KELTICAN /06870301/	ANTIANEMIC PREPARATIONS	Other: Vitamins	0.4mg folicacid+50mg uridine+3ugB12	15Jan2015	24Feb2015	
		25FEB2015	16JUN2015	Dexamethason (FC)	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: PONV-prevention intra-OP	4 mg	25Feb2015	25Feb2015	
		25FEB2015	16JUN2015	Dexamethason (FC)	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: PONV-prevention intra-OP	4 mg	25Feb2015	25Feb2015	
		25FEB2015	16JUN2015	Dexamethason (FC)	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Other: PONV-prevention intra-OP	4 mg	25Feb2015	25Feb2015	
		25FEB2015	16JUN2015	Dexamethason (FC)	DEXAMETHASONE	VASOPROTECTIVES	Other: PONV-prevention intra-OP	4 mg	25Feb2015	25Feb2015	
		25FEB2015	16JUN2015	Dexamethason (FC)	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Other: PONV-prevention intra-OP	4 mg	25Feb2015	25Feb2015	
		25FEB2015	16JUN2015	Dexamethason (FC)	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: PONV-prevention intra-OP	4 mg	25Feb2015	25Feb2015	
		25FEB2015	16JUN2015	Dexamethason (FC)	DEXAMETHASONE	OTOLOGICALS	Other: PONV-prevention intra-OP	4 mg	25Feb2015	25Feb2015	
		25FEB2015	16JUN2015	Dexamethason (FC)	DEXAMETHASONE	NASAL PREPARATIONS	Other: PONV-prevention intra-OP	4 mg	25Feb2015	25Feb2015	
		25FEB2015	16JUN2015	Dexamethason (FC)	DEXAMETHASONE	OPHTHALMOLOGICA LS	Other: PONV-prevention intra-OP	4 mg	25Feb2015	25Feb2015	
		25FEB2015	16JUN2015	Dexamethason (FC)	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: PONV-prevention intra-OP	4 mg	25Feb2015	25Feb2015	
		25FEB2015	16JUN2015	Dexamethason (FC)	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: PONV-prevention intra-OP	4 mg	25Feb2015	25Feb2015	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
08/0803	ND basic	25FEB2015	16JUN2015	Cephazolin	CEFAZOLIN SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: infection prophylaxis	2 g	16Jun2015	16Jun2015	
		25FEB2015	16JUN2015	Mono Embolex 3000 s.c.	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis	3000 IE	24Feb2015	28Feb2015	
		25FEB2015	16JUN2015	Cephazolin	CEFAZOLIN SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: infection prophylaxis	2 g	25Feb2015	25Feb2015	
		25FEB2015	16JUN2015	Prednisolon injection i.v.	PREDNISOLONE	VASOPROTECTIVES	Pain-other	20 mg	15Jan2015	20Jan2015	
		25FEB2015	16JUN2015	Prednisolon injection i.v.	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Pain-other	20 mg	15Jan2015	20Jan2015	
		25FEB2015	16JUN2015	Prednisolon injection i.v.	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Pain-other	20 mg	15Jan2015	20Jan2015	
		25FEB2015	16JUN2015	Prednisolon injection i.v.	PREDNISOLONE	OTOLOGICALS	Pain-other	20 mg	15Jan2015	20Jan2015	
		25FEB2015	16JUN2015	Prednisolon injection i.v.	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Pain-other	20 mg	15Jan2015	20Jan2015	
		25FEB2015	16JUN2015	Prednisolon injection i.v.	PREDNISOLONE	OPHTHALMOLOGICA LS	Pain-other	20 mg	15Jan2015	20Jan2015	
		25FEB2015	16JUN2015	Prednisolon injection i.v.	PREDNISOLONE	NASAL PREPARATIONS	Pain-other	20 mg	15Jan2015	20Jan2015	
		25FEB2015	16JUN2015	Prednisolon injection i.v.	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-other	20 mg	15Jan2015	20Jan2015	
		25FEB2015	16JUN2015	Prednisolon injection i.v.	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other	20 mg	15Jan2015	20Jan2015	
		25FEB2015	16JUN2015	Olynth nasal spray	XYLOMETAZOLINE HYDROCHLORIDE	NASAL PREPARATIONS	Other: pollinosis (MedHis no. 03)	0.1 %	01Apr2015		Yes MH-3

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0803	ND basic	25FEB2015	16JUN2015	Olynth nasal spray	XYLOMETAZOLINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Other: pollinosis (MedHis no. 03)	0.1 %	01Apr2015		Yes	MH-3
08/0804	ND plus	03JUN2015	21AUG2015	Cephazolin	CEFAZOLIN SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: infection prophylaxis at surgery	2 gr	03Jun2015	03Jun2015		
		03JUN2015	21AUG2015	Pantozol (mono-preparation)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: gastric ulcera prophylaxis with NSAR	40 mg	03Jun2015	10Jun2015		
		03JUN2015	21AUG2015	Lormetazepam	LORMETAZEPAM	PSYCHOLEPTICS	Other: anxiety before surgery (AE no. 02)	1 mg	02Jun2015	05Jun2015		AE-2
		03JUN2015	21AUG2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 03)	1.8 gr	21Jul2017	02Aug2017		AE-3
		03JUN2015	21AUG2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 03)	1.8 gr	21Jul2017	02Aug2017		AE-3
		03JUN2015	21AUG2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 03)	1.8 gr	21Jul2017	02Aug2017		AE-3
		03JUN2015	21AUG2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 03)	1.8 gr	21Jul2017	02Aug2017		AE-3
		03JUN2015	21AUG2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 03)	1.8 gr	21Jul2017	02Aug2017		AE-3
		03JUN2015	21AUG2015	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis during hospitalization	0.4	05Jun2015	06Jun2015		
		03JUN2015	21AUG2015	ASS	ACETYLSALICYLIC ACID	ANTITHROMBOTIC AGENTS	Pain-other: headaches (AE no. 01)	500 mg	20Dec2015	26Dec2015		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0804	ND plus	03JUN2015	21AUG2015	ASS	ACETYLSALICYLIC ACID	STOMATOLOGICAL PREPARATIONS	Pain-other: headaches (AE no. 01)	500 mg	20Dec2015	26Dec2015		AE-1
		03JUN2015	21AUG2015	ASS	ACETYLSALICYLIC ACID	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other: headaches (AE no. 01)	500 mg	20Dec2015	26Dec2015		AE-1
		03JUN2015	21AUG2015	ASS	ACETYLSALICYLIC ACID	ANALGESICS	Pain-other: headaches (AE no. 01)	500 mg	20Dec2015	26Dec2015		AE-1
		03JUN2015	21AUG2015	Vomex	DIMENHYDRINATE	OTHER NERVOUS SYSTEM DRUGS	Other: nausea after opiod-therapy	62 mg	01Jun2015	01Jun2015		
		03JUN2015	21AUG2015	Vomex	DIMENHYDRINATE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: nausea after opiod-therapy	62 mg	01Jun2015	01Jun2015		
		03JUN2015	21AUG2015	Vomex	DIMENHYDRINATE	ANTIEMETICS AND ANTINAUSEANTS	Other: nausea after opiod-therapy	62 mg	01Jun2015	01Jun2015		
		03JUN2015	21AUG2015	Mono-Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: prophylaxis	3000 IE	03Jun2015	03Jun2015		
		03JUN2015	21AUG2015	Paracetamol	PARACETAMOL	ANALGESICS	Pain-other: headaches (AE no. 01)	500 mg	20Dec2015	26Dec2015		AE-1
08/0805	ND basic	25JUN2015	22SEP2015	Euthyrox	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyreosis (MedHis no. 01)	150 ug	01Jan2000		Yes	MH-1
		25JUN2015	22SEP2015	St. John's Wort	HYPERICUM PERFORATUM	HOMEOPATHIC PREPARATION	Other: depressive episode (AE no. 11)	900 mg	01Jun2018		Yes	AE-11
		25JUN2015	22SEP2015	St. John's Wort	HYPERICUM PERFORATUM	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	Other: depressive episode (AE no. 11)	900 mg	01Jun2018		Yes	AE-11
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 12)	400 mg	15Feb2019		Yes	AE-12

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0805	ND basic	25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 12)	400 mg	15Feb2019		Yes	AE-12
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 12)	400 mg	15Feb2019		Yes	AE-12
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 12)	400 mg	15Feb2019		Yes	AE-12
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 12)	400 mg	15Feb2019		Yes	AE-12
		25JUN2015	22SEP2015	Mono Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis	3000 IU	25Jun2015	28Jun2015		
		25JUN2015	22SEP2015	Doxycyclin	DOXYCYCLINE	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: Erythema migrans (AE no. 05)	200 mg/d	11Jul2016	01Aug2016		AE-5
		25JUN2015	22SEP2015	Doxycyclin	DOXYCYCLINE	ANTI-ACNE PREPARATIONS	Other: Erythema migrans (AE no. 05)	200 mg/d	11Jul2016	01Aug2016		AE-5
		25JUN2015	22SEP2015	Doxycyclin	DOXYCYCLINE	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Erythema migrans (AE no. 05)	200 mg/d	11Jul2016	01Aug2016		AE-5
		25JUN2015	22SEP2015	Doxycyclin	DOXYCYCLINE	STOMATOLOGICAL PREPARATIONS	Other: Erythema migrans (AE no. 05)	200 mg/d	11Jul2016	01Aug2016		AE-5
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Other: pain (L) knee (AE no. 10)	600 mg	01Jun2018	01Jul2018		AE-10
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Other: pain (L) knee (AE no. 10)	600 mg	01Jun2018	01Jul2018		AE-10

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0805	ND basic	25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: pain (L) knee (AE no. 10)	600 mg	01Jun2018	01Jul2018		AE-10
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Other: pain (L) knee (AE no. 10)	600 mg	01Jun2018	01Jul2018		AE-10
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: pain (L) knee (AE no. 10)	600 mg	01Jun2018	01Jul2018		AE-10
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 13)	2400 mg	01Mar2018	07Mar2018		AE-13
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 13)	2400 mg	01Mar2018	07Mar2018		AE-13
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 13)	2400 mg	01Mar2018	07Mar2018		AE-13
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 13)	2400 mg	01Mar2018	07Mar2018		AE-13
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 13)	2400 mg	01Mar2018	07Mar2018		AE-13
		25JUN2015	22SEP2015	Dormicum	MIDAZOLAM	PSYCHOLEPTICS	Other: fear	7.5 mg	21Sep2015	21Sep2015		
		25JUN2015	22SEP2015	Desogestrel	DESOGESTREL	SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	Other: Contraception	0.075 mg	01Jan2000		Yes	
		25JUN2015	22SEP2015	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Gastritis prophylaxis	40 mg/d	28Jul2016	15Aug2016		
		25JUN2015	22SEP2015	Amoxiclav	AMOXICILLIN W/CLAVULANATE POTASSIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Antibiotics (AE no. 09)	1500/375 mg	01Apr2018	07Apr2018		AE-9
		25JUN2015	22SEP2015	Cefazolin	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: infection prophylaxis	2 g	25Jun2015	25Jun2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0805	ND basic	25JUN2015	22SEP2015	Mono Embolex	CERTOPARIN SODIUM	ANTIITHROMBOTIC AGENTS	Other: thrombosis prophylaxis	3000	22Sep2015	22Sep2015		
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: dental implants (AE no. 09)	600 mg	01Apr2018	07Apr2018		AE-9
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Other: dental implants (AE no. 09)	600 mg	01Apr2018	07Apr2018		AE-9
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: dental implants (AE no. 09)	600 mg	01Apr2018	07Apr2018		AE-9
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Other: dental implants (AE no. 09)	600 mg	01Apr2018	07Apr2018		AE-9
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Other: dental implants (AE no. 09)	600 mg	01Apr2018	07Apr2018		AE-9
08/0806	ND plus	08JUL2015	29SEP2015	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ulcer prophylaxis	20 mg	08Jul2015	12Jul2015		
		08JUL2015	29SEP2015	Dolo Dobendan	CEPACOL ANESTHETIC	STOMATOLOGICAL PREPARATIONS	Other: throat pain	1.5/10 mg	08Jul2015	08Jul2015		
		08JUL2015	29SEP2015	Dolo Dobendan	CEPACOL ANESTHETIC	THROAT PREPARATIONS	Other: throat pain	1.5/10 mg	08Jul2015	08Jul2015		
		08JUL2015	29SEP2015	Dolo Dobendan	CEPACOL ANESTHETIC	ANESTHETICS	Other: throat pain	1.5/10 mg	08Jul2015	08Jul2015		
		08JUL2015	29SEP2015	Dormicum	MIDAZOLAM	PSYCHOLEPTICS	Other: anxiety-fear (MedHis no. 02)	7.5 mg	08Jul2015	08Jul2015		MH-2
		08JUL2015	29SEP2015	PARACETAMOL	PARACETAMOL	ANALGESICS	Pain-other: headaches (AE no. 02)	500 mg	25Feb2016	25Feb2016		AE-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0806	ND plus	08JUL2015	29SEP2015	Fluoxetine	FLUOXETINE HYDROCHLORIDE	PSYCHOANALEPTIC S	Other: Depressive state (AE no. 05)	10 mg	04Jun2017		Yes	AE-5
		08JUL2015	29SEP2015	Mono Embolex 3000	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis	3000	08Jul2015	11Jul2015		
		08JUL2015	29SEP2015	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: SAE (AE no. 3)	80 mg	13Jul2015	16Jul2015		AE-3
		08JUL2015	29SEP2015	Buscopan	HYOSCINE BUTYLBROMIDE	DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	Other: epigastric pain (AE no. 3)	20 mg	13Jul2015	13Jul2015		AE-3
		08JUL2015	29SEP2015	TAVOR (Lorazepam)	LORAZEPAM	ANTIEPILEPTICS	Other: anxiety (MedHis no. 02)	1 mg	28Sep2015	28Sep2015		MH-2
		08JUL2015	29SEP2015	TAVOR (Lorazepam)	LORAZEPAM	PSYCHOLEPTICS	Other: anxiety (MedHis no. 02)	1 mg	28Sep2015	28Sep2015		MH-2
		08JUL2015	29SEP2015	Opipramol	OPIPRAMOL	PSYCHOANALEPTIC S	Other: Anxiety disorder (AE no. 06)	100 mg	04Jun2017		Yes	AE-6
		08JUL2015	29SEP2015	Marvelon	MARVELON	SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	Other: birth controll	0.15/0.03 mg	01Jan1991		Yes	
		08JUL2015	29SEP2015	Cefazolin	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: infection prophylaxis	2 g	08Jul2015	08Jul2015		
		08JUL2015	29SEP2015	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: SAE (AE no. 3)	40 mg	17Jul2015	31Jul2015		AE-3
		08JUL2015	29SEP2015	Laxans (Bisacodyl)	BISACODYL	DRUGS FOR CONSTIPATION	Other: obstipation (AE no. 03)	10 mg	15Jul2015	15Jul2015		AE-3
		08JUL2015	29SEP2015	TAVOR (Lorazepam)	LORAZEPAM	ANTIEPILEPTICS	Other: ANXIETY (MedHis no. 02)	1 mg	06Nov2015	06Nov2015		MH-2
		08JUL2015	29SEP2015	TAVOR (Lorazepam)	LORAZEPAM	PSYCHOLEPTICS	Other: ANXIETY (MedHis no. 02)	1 mg	06Nov2015	06Nov2015		MH-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0806	ND plus	08JUL2015	29SEP2015	Lorazepam	LORAZEPAM	ANTIEPILEPTICS	Other: Anxiety before MRI	1 mg	12Oct2017	12Oct2017		
		08JUL2015	29SEP2015	Lorazepam	LORAZEPAM	PSYCHOLEPTICS	Other: Anxiety before MRI	1 mg	12Oct2017	12Oct2017		
		08JUL2015	29SEP2015	Ganisetron	GRANISETRON	ANTIEMETICS AND ANTINAUSEANTS	Other: nausea	1 mg	08Jul2015	08Jul2015		
		08JUL2015	29SEP2015	Ulcogant	SUCRALFATE	OTHER DERMATOLOGICAL PREPARATIONS	Other: gastric pain (AE no. 3)	1 g	12Jul2015	12Jul2015		AE-3
		08JUL2015	29SEP2015	Ulcogant	SUCRALFATE	STOMATOLOGICAL PREPARATIONS	Other: gastric pain (AE no. 3)	1 g	12Jul2015	12Jul2015		AE-3
		08JUL2015	29SEP2015	Ulcogant	SUCRALFATE	DRUGS FOR ACID RELATED DISORDERS	Other: gastric pain (AE no. 3)	1 g	12Jul2015	12Jul2015		AE-3
		08JUL2015	29SEP2015	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: ulcer prophylaxis	40 mg	25Sep2015	04Oct2015		
		08JUL2015	29SEP2015	Paracetamol	PARACETAMOL	ANALGESICS	Pain-other (AE no. 01)	500 mg	01Dec2015	02Dec2015		AE-1
		08JUL2015	29SEP2015	TAVOR (Lorazepam)	LORAZEPAM	ANTIEPILEPTICS	Other: ANXIETY (MedHis no. 02)	1 mg	14Mar2016	14Mar2016		MH-2
08/0807	ND plus	19NOV2015	02FEB2016	Amlodipin	AMLODIPINE	CALCIUM CHANNEL BLOCKERS	Other: AE art. hypertension (AE no. 02)	5 mg	15Jan2016	10Jan2017		AE-2
		19NOV2015	02FEB2016	Cephazolin	CEFAZOLIN SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: infection prophylaxis	2 g	19Nov2015	19Nov2015		
		19NOV2015	02FEB2016	Metoprolol	METOPROLOL	BETA BLOCKING AGENTS	Other: Art. hypertension (AE no. 06)	50 mg	10Jan2017	16Oct2017		AE-6
		19NOV2015	02FEB2016	Ramipril	RAMIPRIL	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	Other: blood pressure/irregular heart beat (AE no. 08)	5 mg	16Oct2017		Yes	AE-8

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0807	ND plus	19NOV2015	02FEB2016	HCT	HYDROCHLOROTHIA ZIDE	DIURETICS	Other: AE art. hypertension (AE no. 02)	12.5 mg	15Jan2016	10Jan2017		AE-2
		19NOV2015	02FEB2016	Lorazepam	LORAZEPAM	ANTIEPILEPTICS	Other: sleeping difficulty (AE no. 05)	1 mg	18Nov2015	23Nov2015		AE-5
		19NOV2015	02FEB2016	Lorazepam	LORAZEPAM	PSYCHOLEPTICS	Other: sleeping difficulty (AE no. 05)	1 mg	18Nov2015	23Nov2015		AE-5
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: anti-inflamator y	4 mg	19Nov2015	19Nov2015		
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: anti-inflamator y	4 mg	19Nov2015	19Nov2015		
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Other: anti-inflamator y	4 mg	19Nov2015	19Nov2015		
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	Other: anti-inflamator y	4 mg	19Nov2015	19Nov2015		
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	Other: anti-inflamator y	4 mg	19Nov2015	19Nov2015		
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: anti-inflamator y	4 mg	19Nov2015	19Nov2015		
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: anti-inflamator y	4 mg	19Nov2015	19Nov2015		
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: anti-inflamator y	4 mg	19Nov2015	19Nov2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0807	ND plus	19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	OTOLOGICALS	Other: anti-inflamator y	4 mg	19Nov2015	19Nov2015		
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	Other: anti-inflamator y	4 mg	19Nov2015	19Nov2015		
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Other: anti-inflamator y	4 mg	19Nov2015	19Nov2015		
		19NOV2015	02FEB2016	Votum (Olmesartan)	OLMESARTAN MEDOXOMIL	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Other: AE art. hypertension (AE no. 02)	20 mg	15Jan2016	10Jan2017		AE-2
		19NOV2015	02FEB2016	Vomex A (Dimenhydrinat)	DIMENHYDRINATE	ANTIEMETICS AND ANTINAUSEANTS	Other: antiemetic prophylaxis under tramadol medication	62 mg	09Nov2015	10Nov2015		
		19NOV2015	02FEB2016	Vomex A (Dimenhydrinat)	DIMENHYDRINATE	OTHER NERVOUS SYSTEM DRUGS	Other: antiemetic prophylaxis under tramadol medication	62 mg	09Nov2015	10Nov2015		
		19NOV2015	02FEB2016	Vomex A (Dimenhydrinat)	DIMENHYDRINATE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: antiemetic prophylaxis under tramadol medication	62 mg	09Nov2015	10Nov2015		
		19NOV2015	02FEB2016	Lormetazepam	LORMETAZEPAM	PSYCHOLEPTICS	Other: sleeping difficulty (AE no. 05)	2 mg	21Nov2015	21Nov2015		AE-5
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	Other: anti-inflamator y (AE no. 01)	12 mg	11Mar2016	14Mar2016		AE-1
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	Other: anti-inflamator y (AE no. 01)	12 mg	11Mar2016	14Mar2016		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0807	ND plus	19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: anti-inflamator y (AE no. 01)	12 mg	11Mar2016	14Mar2016		AE-1
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: anti-inflamator y (AE no. 01)	12 mg	11Mar2016	14Mar2016		AE-1
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Other: anti-inflamator y (AE no. 01)	12 mg	11Mar2016	14Mar2016		AE-1
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	Other: anti-inflamator y (AE no. 01)	12 mg	11Mar2016	14Mar2016		AE-1
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: anti-inflamator y (AE no. 01)	12 mg	11Mar2016	14Mar2016		AE-1
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	OTOLOGICALS	Other: anti-inflamator y (AE no. 01)	12 mg	11Mar2016	14Mar2016		AE-1
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: anti-inflamator y (AE no. 01)	12 mg	11Mar2016	14Mar2016		AE-1
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Other: anti-inflamator y (AE no. 01)	12 mg	11Mar2016	14Mar2016		AE-1
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: anti-inflamator y (AE no. 01)	12 mg	11Mar2016	14Mar2016		AE-1
		19NOV2015	02FEB2016	Bisoprolol	BISOPROLOL	BETA BLOCKING AGENTS	Other: AE art. hypertension (AE no. 02)	5 mg	15Dec2015	15Jan2016		AE-2
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	Other: anti-inflamator y	4 mg	10Nov2015	10Nov2015		
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: anti-inflamator y	4 mg	10Nov2015	10Nov2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0807	ND plus	19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: anti-inflamator y	4 mg	10Nov2015	10Nov2015		
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	Other: anti-inflamator y	4 mg	10Nov2015	10Nov2015		
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Other: anti-inflamator y	4 mg	10Nov2015	10Nov2015		
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	Other: anti-inflamator y	4 mg	10Nov2015	10Nov2015		
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: anti-inflamator y	4 mg	10Nov2015	10Nov2015		
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	OTOLOGICALS	Other: anti-inflamator y	4 mg	10Nov2015	10Nov2015		
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: anti-inflamator y	4 mg	10Nov2015	10Nov2015		
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Other: anti-inflamator y	4 mg	10Nov2015	10Nov2015		
		19NOV2015	02FEB2016	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: anti-inflamator y	4 mg	10Nov2015	10Nov2015		
		19NOV2015	02FEB2016	Midazolam	MIDAZOLAM	PSYCHOLEPTICS	Other: sedation for surgery	7.5 mg	19Nov2015	19Nov2015		
08/0808	SC	03DEC2015	-	Euthyrox	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyreosis (MedHis no. 02)	50 ug	UNK		Yes	MH-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0808	SC	03DEC2015	-	Cephazolin	CEFAZOLIN SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: infection prophylaxis	2 gr	03Dec2015	03Dec2015		
		03DEC2015	-	Paracetamol	PARACETAMOL	ANALGESICS	Pain-other (AE no. 01)	500 mg	05Jan2016	11Jan2016		AE-1
		03DEC2015	-	prednisolone	PREDNISOLONE	OTOLOGICALS	Other: allergy (AE no. 07)	250 mg	13Jun2018	13Jun2018		AE-7
		03DEC2015	-	prednisolone	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: allergy (AE no. 07)	250 mg	13Jun2018	13Jun2018		AE-7
		03DEC2015	-	prednisolone	PREDNISOLONE	VASOPROTECTIVES	Other: allergy (AE no. 07)	250 mg	13Jun2018	13Jun2018		AE-7
		03DEC2015	-	prednisolone	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: allergy (AE no. 07)	250 mg	13Jun2018	13Jun2018		AE-7
		03DEC2015	-	prednisolone	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: allergy (AE no. 07)	250 mg	13Jun2018	13Jun2018		AE-7
		03DEC2015	-	prednisolone	PREDNISOLONE	NASAL PREPARATIONS	Other: allergy (AE no. 07)	250 mg	13Jun2018	13Jun2018		AE-7
		03DEC2015	-	prednisolone	PREDNISOLONE	OPHTHALMOLOGICA LS	Other: allergy (AE no. 07)	250 mg	13Jun2018	13Jun2018		AE-7
		03DEC2015	-	prednisolone	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: allergy (AE no. 07)	250 mg	13Jun2018	13Jun2018		AE-7
		03DEC2015	-	prednisolone	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: allergy (AE no. 07)	250 mg	13Jun2018	13Jun2018		AE-7
		03DEC2015	-	Euthyrox	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: hypothyroidism (MedHis no. 02)	50 ug	2017	18Sep2017		MH-2
		03DEC2015	-	Ramipril	RAMIPRIL	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Other: Hypertonia (MedHis no. 01)	5 mg	UNK		Yes	MH-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0808	SC	03DEC2015	-	Fenestil	DIMETINDENE MALEATE	ANTI PRURITICS, INCL. ANTI HISTAMINES, ANESTHETICS, ETC.	Other: allergy (AE no. 07)	4 mg	13Jun2018	13Jun2018		AE-7
		03DEC2015	-	Fenestil	DIMETINDENE MALEATE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: allergy (AE no. 07)	4 mg	13Jun2018	13Jun2018		AE-7
		03DEC2015	-	Ramipril	RAMIPRIL	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Other: medical history no. 1 (MedHis no. 01)	5 mg	UNK	17Dec2018		MH-1
		03DEC2015	-	Midazolam	MIDAZOLAM	PSYCHOLEPTICS	Other: sedation for surgery	7.5 mg	03Dec2015	03Dec2015		
		03DEC2015	-	Mono-Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis	3000 IE	04Dec2015	07Dec2015		
		03DEC2015	-	IBEROGAST	IBEROGAST	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	Other: intestinal disorder (AE no. 05)	40 drops	27Mar2017	19Apr2017		AE-5
		03DEC2015	-	Venomil wasp (100ug)	ALLERGENS, INSECT VENOM	ALLERGENS	Other: allergy (AE no. 10)	100 ug	12Dec2018	14Dec2018		AE-10
		03DEC2015	-	Amlodipin	AMLODIPINE	CALCIUM CHANNEL BLOCKERS	Other: medical history no. 1 (MedHis no. 01)	5 mg	18Dec2018		Yes	MH-1
		03DEC2015	-	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	Other: anti-inflamator y therapy	4 g	03Dec2015	03Dec2015		
		03DEC2015	-	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	Other: anti-inflamator y therapy	4 g	03Dec2015	03Dec2015		
		03DEC2015	-	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: anti-inflamator y therapy	4 g	03Dec2015	03Dec2015		
		03DEC2015	-	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: anti-inflamator y therapy	4 g	03Dec2015	03Dec2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0808	SC	03DEC2015	-	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Other: anti-inflamator y therapy	4 g	03Dec2015	03Dec2015		
		03DEC2015	-	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	Other: anti-inflamator y therapy	4 g	03Dec2015	03Dec2015		
		03DEC2015	-	Fortecortin	DEXAMETHASONE	OTOLOGICALS	Other: anti-inflamator y therapy	4 g	03Dec2015	03Dec2015		
		03DEC2015	-	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: anti-inflamator y therapy	4 g	03Dec2015	03Dec2015		
		03DEC2015	-	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS / DERMATOLOGICAL PREPARATIONS	Other: anti-inflamator y therapy	4 g	03Dec2015	03Dec2015		
		03DEC2015	-	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Other: anti-inflamator y therapy	4 g	03Dec2015	03Dec2015		
		03DEC2015	-	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: anti-inflamator y therapy	4 g	03Dec2015	03Dec2015		
		03DEC2015	-	Lormetazepam	LORMETAZEPAM	PSYCHOLEPTICS	Other: sleeping difficulty (AE no. 04)	1 mg	06Dec2015	07Dec2015		AE-4
		03DEC2015	-	L-Thyroxin	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: hypothyroidism (MedHis no. 02)	75 ug	19Sep2017		Yes	MH-2
		03DEC2015	-	Atorvastatin	ATORVASTATIN	LIPID MODIFYING AGENTS	Other: hypercholesteri nemia (AE no. 11)	20 mg	18Sep2017		Yes	AE-11
09/0901	SC	30OCT2014	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: prophylaxis	1-0-0 20 mg	01Sep2014	29Oct2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0901	SC	30OCT2014	-	Cefazolin 2 g	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic treatment	2g-0-0	30Oct2014	30Oct2014		
		30OCT2014	-	Ibuprophen 400 mg	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 01)	if necessary 1x400 mg ca. 2xWoche	17Mar2017	10Sep2017		AE-1
		30OCT2014	-	Ibuprophen 400 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 01)	if necessary 1x400 mg ca. 2xWoche	17Mar2017	10Sep2017		AE-1
		30OCT2014	-	Ibuprophen 400 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 01)	if necessary 1x400 mg ca. 2xWoche	17Mar2017	10Sep2017		AE-1
		30OCT2014	-	Ibuprophen 400 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 01)	if necessary 1x400 mg ca. 2xWoche	17Mar2017	10Sep2017		AE-1
		30OCT2014	-	Ibuprophen 400 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 01)	if necessary 1x400 mg ca. 2xWoche	17Mar2017	10Sep2017		AE-1
		30OCT2014	-	Bisoprolol 1.25 mg	BISOPROLOL	BETA BLOCKING AGENTS	Other: Arrhythmia (AE no. 02)	1-0-0	10Jan2019	22May2019		AE-2
		30OCT2014	-	Certoparin 3000 i.E. sc	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Anti-thrombosis	0-0-1	29Oct2014	29Oct2014		
		30OCT2014	-	Certoparin 3000 i.E. sc	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Anti-thrombosis	0-0-1	31Oct2014	10Nov2014		
09/0903	ND plus	20NOV2014	-	Pantoprazol 20 mg	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: proton pumpinhibitor, gastritis prophylaxis	0-0-1	19Nov2014	19Jan2015		
		20NOV2014	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: proton pump inhibitor, gastritis prophylaxis (AE no. 01)	0-0-1 20 mg	20Jan2015	01Feb2015		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0903	ND plus	20NOV2014	-	Cefazolin 2 gr.	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Infection prophylaxis	2 gr.-0-0	20Nov2014	20Nov2014		
		20NOV2014	-	Certoparin Na s.c.	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis	0-0-1 3000 IU	19Nov2014	02Dec2014		
09/0904	ND basic	09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	ANTIEPILEPTICS	Other: Insomnia prophylaxis	0-0-0-1as needed 1-2/weeks	22Feb2015	25Jul2015		
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	PSYCHOLEPTICS	Other: Insomnia prophylaxis	0-0-0-1as needed 1-2/weeks	22Feb2015	25Jul2015		
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	MUSCLE RELAXANTS	Other: Insomnia prophylaxis	0-0-0-1as needed 1-2/weeks	22Feb2015	25Jul2015		
		09FEB2015	21MAY2015	Sirdalud 2 mg	TIZANIDINE HYDROCHLORIDE	MUSCLE RELAXANTS	Other: muscle cramps prophylaxis	0-0-0-2g	15Sep2015	24Sep2015		
		09FEB2015	21MAY2015	Ibuprofen 400 mg	IBUPROFEN	CARDIAC THERAPY	Other: Rupture left external band ankle joint (AE no. 02)	1-1-1	18Mar2016	02Apr2016		AE-2
		09FEB2015	21MAY2015	Ibuprofen 400 mg	IBUPROFEN	THROAT PREPARATIONS	Other: Rupture left external band ankle joint (AE no. 02)	1-1-1	18Mar2016	02Apr2016		AE-2
		09FEB2015	21MAY2015	Ibuprofen 400 mg	IBUPROFEN	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	Other: Rupture left external band ankle joint (AE no. 02)	1-1-1	18Mar2016	02Apr2016		AE-2
		09FEB2015	21MAY2015	Ibuprofen 400 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Other: Rupture left external band ankle joint (AE no. 02)	1-1-1	18Mar2016	02Apr2016		AE-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0904	ND basic	09FEB2015	21MAY2015	Ibuprofen 400 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: Rupture left external band ankle joint (AE no. 02)	1-1-1	18Mar2016	02Apr2016		AE-2
		09FEB2015	21MAY2015	Tramal Long 50 mg	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-other (AE no. 04)	0-0-1	26Sep2016	07Dec2016		AE-4
		09FEB2015	21MAY2015	Amineurin 25 mg	AMITRIPTYLINE HYDROCHLORIDE	PSYCHOANALEPTIC S	Pain-other (AE no. 04)	0-0-1	12Apr2017	UNK		AE-4
		09FEB2015	21MAY2015	Amineurin 25 mg	AMITRIPTYLINE HYDROCHLORIDE	ANALGESICS	Pain-other (AE no. 04)	0-0-1	12Apr2017	UNK		AE-4
		09FEB2015	21MAY2015	Decortin 10 mg Tabl.	PREDNISONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 06)	1-1-1	02Mar2020	04Mar2020		AE-6
		09FEB2015	21MAY2015	Decortin 10 mg Tabl.	PREDNISONE	OPHTHALMOLOGICA LS	Pain-other (AE no. 06)	1-1-1	02Mar2020	04Mar2020		AE-6
		09FEB2015	21MAY2015	Decortin 10 mg Tabl.	PREDNISONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Pain-other (AE no. 06)	1-1-1	02Mar2020	04Mar2020		AE-6
		09FEB2015	21MAY2015	Tramadol 100 mg	TRAMADOL	ANALGESICS	Pain-other (AE no. 06)	0-1-0	06Mar2020	06Mar2020		AE-6
		09FEB2015	21MAY2015	Tramadol 100 mg	TRAMADOL	ANALGESICS	Pain-other (AE no. 06)	0-1-0	20Mar2020	20Mar2020		AE-6
		09FEB2015	21MAY2015	Pregabador 75 mg	PREGABALIN	ANALGESICS	Other: Insomnia prophylaxis	1-0-1	14Aug2015	14Sep2015		
		09FEB2015	21MAY2015	Pregabador 75 mg	PREGABALIN	ANTIEPILEPTICS	Other: Insomnia prophylaxis	1-0-1	14Aug2015	14Sep2015		
		09FEB2015	21MAY2015	Pregabador 75 mg	PREGABALIN	PSYCHOLEPTICS	Other: Insomnia prophylaxis	1-0-1	14Aug2015	14Sep2015		
		09FEB2015	21MAY2015	Ibuprophen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: pain shoulder right (AE no. 01)	600mg-0-600mg	31Aug2015	14Sep2015		AE-1
		09FEB2015	21MAY2015	Ibuprophen 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: pain shoulder right (AE no. 01)	600mg-0-600mg	31Aug2015	14Sep2015		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0904	ND basic	09FEB2015	21MAY2015	Ibuprophen 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Other: pain shoulder right (AE no. 01)	600mg-0-600mg	31Aug2015	14Sep2015		AE-1
		09FEB2015	21MAY2015	Ibuprophen 600 mg	IBUPROFEN	CARDIAC THERAPY	Other: pain shoulder right (AE no. 01)	600mg-0-600mg	31Aug2015	14Sep2015		AE-1
		09FEB2015	21MAY2015	Ibuprophen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Other: pain shoulder right (AE no. 01)	600mg-0-600mg	31Aug2015	14Sep2015		AE-1
		09FEB2015	21MAY2015	Ibuprofen 400 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: Rupture left external band ankle joint (AE no. 02)	0-1-1	03Apr2016	18Apr2016		AE-2
		09FEB2015	21MAY2015	Ibuprofen 400 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Other: Rupture left external band ankle joint (AE no. 02)	0-1-1	03Apr2016	18Apr2016		AE-2
		09FEB2015	21MAY2015	Ibuprofen 400 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: Rupture left external band ankle joint (AE no. 02)	0-1-1	03Apr2016	18Apr2016		AE-2
		09FEB2015	21MAY2015	Ibuprofen 400 mg	IBUPROFEN	THROAT PREPARATIONS	Other: Rupture left external band ankle joint (AE no. 02)	0-1-1	03Apr2016	18Apr2016		AE-2
		09FEB2015	21MAY2015	Ibuprofen 400 mg	IBUPROFEN	CARDIAC THERAPY	Other: Rupture left external band ankle joint (AE no. 02)	0-1-1	03Apr2016	18Apr2016		AE-2
		09FEB2015	21MAY2015	Novalgin Tropfen 25°	METAMIZOLE SODIUM	ANALGESICS	Pain-other (AE no. 04)	25° 2-3x/D	08Dec2016	03Apr2017		AE-4

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0904	ND basic	09FEB2015	21MAY2015	Tamsolusin 0.4 mg	TAMSULOSIN	UROLOGICALS	Other: Benign prostate hyperplasia (AE no. 05)	0-0-1	08Nov2016	UNK		AE-5
		09FEB2015	21MAY2015	Decortin 10 mg Tabl.	PREDNISONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	Pain-other (AE no. 06)	1-0-1	05Mar2020	07Mar2020		AE-6
		09FEB2015	21MAY2015	Decortin 10 mg Tabl.	PREDNISONE	OPHTHALMOLOGICALS	Pain-other (AE no. 06)	1-0-1	05Mar2020	07Mar2020		AE-6
		09FEB2015	21MAY2015	Decortin 10 mg Tabl.	PREDNISONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 06)	1-0-1	05Mar2020	07Mar2020		AE-6
		09FEB2015	21MAY2015	Tramadol 100 mg	TRAMADOL	ANALGESICS	Pain-other (AE no. 06)	0-1-0	10Mar2020	10Mar2020		AE-6
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	PSYCHOLEPTICS	Pain-other (AE no. 06)	0-1-0 +NaCl 0.9 % 100 ml i.v.	20Mar2020	20Mar2020		AE-6
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	ANTIEPILEPTICS	Pain-other (AE no. 06)	0-1-0 +NaCl 0.9 % 100 ml i.v.	20Mar2020	20Mar2020		AE-6
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	MUSCLE RELAXANTS	Pain-other (AE no. 06)	0-1-0 +NaCl 0.9 % 100 ml i.v.	20Mar2020	20Mar2020		AE-6
		09FEB2015	21MAY2015	Cefazolin 2 g	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic treatment	1-0-0	09Feb2015	09Feb2015		
		09FEB2015	21MAY2015	Certoparin 3000 i.E. sc	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Antithrombotic	0-0-1	08Feb2015	08Feb2015		
		09FEB2015	21MAY2015	Bucain 0.5%	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICALS	Pain-other (AE no. 01)	1	10Jan2016	10Jan2016		AE-1
		09FEB2015	21MAY2015	Bucain 0.5%	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain-other (AE no. 01)	1	10Jan2016	10Jan2016		AE-1
		09FEB2015	21MAY2015	Ibuprophen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 04)	0-0-1	08Dec2016	03Apr2017		AE-4

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0904	ND basic	09FEB2015	21MAY2015	Ibuprophen 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 04)	0-0-1	08Dec2016	03Apr2017		AE-4
		09FEB2015	21MAY2015	Ibuprophen 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 04)	0-0-1	08Dec2016	03Apr2017		AE-4
		09FEB2015	21MAY2015	Ibuprophen 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 04)	0-0-1	08Dec2016	03Apr2017		AE-4
		09FEB2015	21MAY2015	Ibuprophen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 04)	0-0-1	08Dec2016	03Apr2017		AE-4
		09FEB2015	21MAY2015	Decortin 10 mg Tabl.	PREDNISONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 06)	1-0-0	08Mar2020	10Mar2020		AE-6
		09FEB2015	21MAY2015	Decortin 10 mg Tabl.	PREDNISONE	OPHTHALMOLOGICA LS	Pain-other (AE no. 06)	1-0-0	08Mar2020	10Mar2020		AE-6
		09FEB2015	21MAY2015	Decortin 10 mg Tabl.	PREDNISONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Pain-other (AE no. 06)	1-0-0	08Mar2020	10Mar2020		AE-6
		09FEB2015	21MAY2015	Tramadol 100 mg	TRAMADOL	ANALGESICS	Pain-other (AE no. 06)	0-1-0	13Mar2020	13Mar2020		AE-6
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	MUSCLE RELAXANTS	Other: Insomnia prophylaxis	0-0-0-1	14Feb2015	21Feb2015		
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	ANTIEPILEPTICS	Other: Insomnia prophylaxis	0-0-0-1	14Feb2015	21Feb2015		
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	PSYCHOLEPTICS	Other: Insomnia prophylaxis	0-0-0-1	14Feb2015	21Feb2015		
		09FEB2015	21MAY2015	Certoparin 3000 i.E. sc	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Antithrombotic	0-0-1	10Feb2015	13Feb2015		
		09FEB2015	21MAY2015	Triamcinolon 20 mg	TRIAMCINOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 01)	1	10Jan2016	10Jan2016		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0904	ND basic	09FEB2015	21MAY2015	Triamcinolon 20 mg	TRIAMCINOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 01)	1	10Jan2016	10Jan2016		AE-1
		09FEB2015	21MAY2015	Triamcinolon 20 mg	TRIAMCINOLONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-other (AE no. 01)	1	10Jan2016	10Jan2016		AE-1
		09FEB2015	21MAY2015	Triamcinolon 20 mg	TRIAMCINOLONE	OPHTHALMOLOGICALS	Pain-other (AE no. 01)	1	10Jan2016	10Jan2016		AE-1
		09FEB2015	21MAY2015	Triamcinolon 20 mg	TRIAMCINOLONE	NASAL PREPARATIONS	Pain-other (AE no. 01)	1	10Jan2016	10Jan2016		AE-1
		09FEB2015	21MAY2015	Triamcinolon 20 mg	TRIAMCINOLONE	VASOPROTECTIVES	Pain-other (AE no. 01)	1	10Jan2016	10Jan2016		AE-1
		09FEB2015	21MAY2015	Triamcinolon 20 mg	TRIAMCINOLONE	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 01)	1	10Jan2016	10Jan2016		AE-1
		09FEB2015	21MAY2015	Amineurin 25 mg	AMITRIPTYLIN HYDROCHLORIDE	ANALGESICS	Pain-other (AE no. 04)	0-0-1/2	04Apr2016	11Apr2016		AE-4
		09FEB2015	21MAY2015	Amineurin 25 mg	AMITRIPTYLIN HYDROCHLORIDE	PSYCHOANALEPTICS	Pain-other (AE no. 04)	0-0-1/2	04Apr2016	11Apr2016		AE-4
		09FEB2015	21MAY2015	Decortin 10 mg Tabl.	PREDNISONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	Pain-other (AE no. 06)	1/2-0-0	11Mar2020	13Mar2020		AE-6
		09FEB2015	21MAY2015	Decortin 10 mg Tabl.	PREDNISONE	OPHTHALMOLOGICALS	Pain-other (AE no. 06)	1/2-0-0	11Mar2020	13Mar2020		AE-6
		09FEB2015	21MAY2015	Decortin 10 mg Tabl.	PREDNISONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 06)	1/2-0-0	11Mar2020	13Mar2020		AE-6
		09FEB2015	21MAY2015	Tramadol 100 mg	TRAMADOL	ANALGESICS	Pain-other (AE no. 06)	0-1-0	16Mar2020	16Mar2020		AE-6
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	MUSCLE RELAXANTS	Pain-other (AE no. 06)	0-1-0 +100 ml Nacl 0.9 % i.v.	06Mar2020	06Mar2020		AE-6
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	PSYCHOLEPTICS	Pain-other (AE no. 06)	0-1-0 +100 ml Nacl 0.9 % i.v.	06Mar2020	06Mar2020		AE-6
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	ANTIEPILEPTICS	Pain-other (AE no. 06)	0-1-0 +100 ml Nacl 0.9 % i.v.	06Mar2020	06Mar2020		AE-6
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	PSYCHOLEPTICS	Pain-other (AE no. 06)	0-1-0 +100 ml Nacl 0.9 % i.v.	10Mar2020	10Mar2020		AE-6

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0904	ND basic	09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	ANTIEPILEPTICS	Pain-other (AE no. 06)	0-1-0 +100 ml Nacl 0.9 % i.v.	10Mar2020	10Mar2020		AE-6
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	MUSCLE RELAXANTS	Pain-other (AE no. 06)	0-1-0 +100 ml Nacl 0.9 % i.v.	10Mar2020	10Mar2020		AE-6
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	MUSCLE RELAXANTS	Pain-other (AE no. 06)	0-1-0 +100 ml Nacl 0.9 % i.v.	13Mar2020	13Mar2020		AE-6
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	ANTIEPILEPTICS	Pain-other (AE no. 06)	0-1-0 +100 ml Nacl 0.9 % i.v.	13Mar2020	13Mar2020		AE-6
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	PSYCHOLEPTICS	Pain-other (AE no. 06)	0-1-0 +100 ml Nacl 0.9 % i.v.	13Mar2020	13Mar2020		AE-6
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	PSYCHOLEPTICS	Pain-other (AE no. 06)	0-1-0 +100 ml Nacl 0.9 % i.v.	16Mar2020	16Mar2020		AE-6
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	ANTIEPILEPTICS	Pain-other (AE no. 06)	0-1-0 +100 ml Nacl 0.9 % i.v.	16Mar2020	16Mar2020		AE-6
		09FEB2015	21MAY2015	Diacepam 10 mg	DIAZEPAM	MUSCLE RELAXANTS	Pain-other (AE no. 06)	0-1-0 +100 ml Nacl 0.9 % i.v.	16Mar2020	16Mar2020		AE-6
09/0905	ND plus	19MAR2015	25JUN2015	Cefazolin 2 g	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic treatment	1-0-0 2gr.	19Mar2015	19Mar2015		
		19MAR2015	25JUN2015	Eye nosecreme Bepanthen	DEXPANTHENOL	DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	Other: ENT-OP polyp removal (AE no. 02)	1 x daily	23Sep2015	30Sep2015		AE-2
		19MAR2015	25JUN2015	Eye nosecreme Bepanthen	DEXPANTHENOL	VITAMINS	Other: ENT-OP polyp removal (AE no. 02)	1 x daily	23Sep2015	30Sep2015		AE-2
		19MAR2015	25JUN2015	Eye nosecreme Bepanthen	DEXPANTHENOL	NASAL PREPARATIONS	Other: ENT-OP polyp removal (AE no. 02)	1 x daily	23Sep2015	30Sep2015		AE-2
		19MAR2015	25JUN2015	Eye nosecreme Bepanthen	DEXPANTHENOL	OPHTHALMOLOGICALS	Other: ENT-OP polyp removal (AE no. 02)	1 x daily	23Sep2015	30Sep2015		AE-2
		19MAR2015	25JUN2015	Eye nosecreme Bepanthen	DEXPANTHENOL	PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	Other: ENT-OP polyp removal (AE no. 02)	1 x daily	23Sep2015	30Sep2015		AE-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0905	ND plus	19MAR2015	25JUN2015	Pantoprazol 40 mg Tabl.	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: stomach protection (AE no. 03)	1-0-0	28Sep2018	19Oct2018		AE-3
		19MAR2015	25JUN2015	Pantoprazol 20 mg	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: stomach protection (AE no. 03)	20 mg 1-0-0	20Oct2018	19Apr2019		AE-3
		19MAR2015	25JUN2015	Certoparin 3000 i.e.	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Anti-thrombosis prophylaxis (AE no. 04)	3000 IU Sc	11Mar2019	25Mar2019		AE-4
		19MAR2015	25JUN2015	Panthenol nose spray	PANTHENOL	PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	Other: ENT-OP polyp removal (AE no. 02)	3-4 x daily	23Sep2015	15Oct2015		AE-2
		19MAR2015	25JUN2015	Panthenol nose spray	PANTHENOL	VITAMINS	Other: ENT-OP polyp removal (AE no. 02)	3-4 x daily	23Sep2015	15Oct2015		AE-2
		19MAR2015	25JUN2015	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: prophylaxe	0-0-20 mg	14Mar2015	10May2015		
		19MAR2015	25JUN2015	Amoxicillin Rat. 750 mg	AMOXICILLIN TRIHYDRATE	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic treatment after OP (AE no. 02)	1-1-1	22Sep2015	23Sep2015		AE-2
		19MAR2015	25JUN2015	Clexane 40 mg	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis after polypen surgery (AE no. 02)	1	22Sep2015	23Sep2015		AE-2
09/0906		19MAR2015	25JUN2015	Novalgin (Metamizol) 1 gr.	METAMIZOLE SODIUM	ANALGESICS	Pain-other (AE no. 02)	1-1-1-1	22Sep2015	23Sep2015		AE-2
		-	-	LThyroxin 75 mg	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hashimoto Thyrioditis	1-0-0	UN		Yes	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0907	SC	15APR2015	-	Certoparin 3000 i.E. sc	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Anti-thrombosis	0-0-1	14Apr2015	14Apr2015		
		15APR2015	-	Ciprofloxacin 500 mg	CIPROFLOXACIN	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Diverticulitis (AE no. 01)	1-0-1	05Oct2016	11Oct2016		AE-1
		15APR2015	-	Ciprofloxacin 500 mg	CIPROFLOXACIN	OTOLOGICALS	Other: Diverticulitis (AE no. 01)	1-0-1	05Oct2016	11Oct2016		AE-1
		15APR2015	-	Ciprofloxacin 500 mg	CIPROFLOXACIN	OPHTHALMOLOGICA LS	Other: Diverticulitis (AE no. 01)	1-0-1	05Oct2016	11Oct2016		AE-1
		15APR2015	-	Ciprofloxacin 500 mg	CIPROFLOXACIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Diverticulitis (AE no. 01)	1-0-1	05Oct2016	11Oct2016		AE-1
		15APR2015	-	Ciprofloxacin 500 mg	CIPROFLOXACIN	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: Diverticulitis (AE no. 01)	1-0-1	05Oct2016	11Oct2016		AE-1
		15APR2015	-	Ciprofloxacin 500 mg	CIPROFLOXACIN	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: Diverticulitis (AE no. 01)	1-0-1	05Oct2016	11Oct2016		AE-1
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	OTHER DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	OTHER GYNECOLOGICALS	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	UROLOGICALS	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0907	SC	15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETA L SYSTEM	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	OPHTHALMOLOGICA LS	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	THROAT PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	NASAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	ALL OTHER NON-THERAPEUTIC PRODUCTS	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	VASOPROTECTIVES	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	OTHER DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	13Nov2018	13Nov2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	Pain-other (AE no. 02)	2 ml i.a.	13Nov2018	13Nov2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	UROLOGICALS	Pain-other (AE no. 02)	2 ml i.a.	13Nov2018	13Nov2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	OTHER GYNECOLOGICALS	Pain-other (AE no. 02)	2 ml i.a.	13Nov2018	13Nov2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETA L SYSTEM	Pain-other (AE no. 02)	2 ml i.a.	13Nov2018	13Nov2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	OPHTHALMOLOGICA LS	Pain-other (AE no. 02)	2 ml i.a.	13Nov2018	13Nov2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	THROAT PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	13Nov2018	13Nov2018		AE-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0907	SC	15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	NASAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	13Nov2018	13Nov2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	ALL OTHER NON-THERAPEUTIC PRODUCTS	Pain-other (AE no. 02)	2 ml i.a.	13Nov2018	13Nov2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	VASOPROTECTIVES	Pain-other (AE no. 02)	2 ml i.a.	13Nov2018	13Nov2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	13Nov2018	13Nov2018		AE-2
		15APR2015	-	Cefazolin 2 gr	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic treatment	1-0-0	15Apr2015	15Apr2015		
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	VASOPROTECTIVES	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	ALL OTHER NON-THERAPEUTIC PRODUCTS	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	THROAT PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	NASAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	OPHTHALMOLOGICA LS	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETA L SYSTEM	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	OTHER DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	UROLOGICALS	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0907	SC	15APR2015	-	Synocrom	HYALURONIC ACID	OTHER	Pain-other (AE	2 ml i.a.	10Oct2018	10Oct2018		AE-2
			-	Hyaluronic acid		GYNECOLOGICALS	no. 02)					
		15APR2015	-	Lipotalon	DEXAMETHASONE	STOMATOLOGICAL	Pain-other (AE	2 ml i.a.	13Nov2018	13Nov2018		AE-2
			-		PALMITATE	PREPARATIONS	no. 02)					
		15APR2015	-	Lipotalon	DEXAMETHASONE	VASOPROTECTIVES	Pain-other (AE	2 ml i.a.	13Nov2018	13Nov2018		AE-2
			-		PALMITATE		no. 02)					
		15APR2015	-	Lipotalon	DEXAMETHASONE	OPHTHALMOLOGICA	Pain-other (AE	2 ml i.a.	13Nov2018	13Nov2018		AE-2
			-		PALMITATE	L AND	no. 02)					
			-			OTOLOGICAL						
			-			PREPARATIONS						
		15APR2015	-	Lipotalon	DEXAMETHASONE	NASAL	Pain-other (AE	2 ml i.a.	13Nov2018	13Nov2018		AE-2
			-		PALMITATE	PREPARATIONS	no. 02)					
		15APR2015	-	Lipotalon	DEXAMETHASONE	OTOLOGICALS	Pain-other (AE	2 ml i.a.	13Nov2018	13Nov2018		AE-2
			-		PALMITATE		no. 02)					
		15APR2015	-	Lipotalon	DEXAMETHASONE	OPHTHALMOLOGICA	Pain-other (AE	2 ml i.a.	13Nov2018	13Nov2018		AE-2
			-		PALMITATE	LS	no. 02)					
		15APR2015	-	Lipotalon	DEXAMETHASONE	ANTI-ACNE	Pain-other (AE	2 ml i.a.	13Nov2018	13Nov2018		AE-2
			-		PALMITATE	PREPARATIONS	no. 02)					
		15APR2015	-	Lipotalon	DEXAMETHASONE	CORTICOSTEROIDS	Pain-other (AE	2 ml i.a.	13Nov2018	13Nov2018		AE-2
			-		PALMITATE	FOR SYSTEMIC	no. 02)					
			-			USE						
		15APR2015	-	Certoparin 3000	CERTOPARIN	ANTITHROMBOTIC	Other:	0-0-1	16Apr2015	17Apr2015		
			-	i.e. sc	SODIUM	AGENTS	Anti-thrombosis					
		15APR2015	-	Synocrom	HYALURONIC ACID	OTHER	Pain-other (AE	2 ml i.a.	17Oct2018	17Oct2018		AE-2
			-	Hyaluronic acid		DERMATOLOGICAL	no. 02)					
			-			PREPARATIONS						
		15APR2015	-	Synocrom	HYALURONIC ACID	UROLOGICALS	Pain-other (AE	2 ml i.a.	17Oct2018	17Oct2018		AE-2
			-	Hyaluronic acid			no. 02)					
		15APR2015	-	Synocrom	HYALURONIC ACID	OTHER	Pain-other (AE	2 ml i.a.	17Oct2018	17Oct2018		AE-2
			-	Hyaluronic acid		GYNECOLOGICALS	no. 02)					
		15APR2015	-	Synocrom	HYALURONIC ACID	PREPARATIONS	Pain-other (AE	2 ml i.a.	17Oct2018	17Oct2018		AE-2
			-	Hyaluronic acid		FOR TREATMENT	no. 02)					
			-			OF WOUNDS AND						
			-			ULCERS						
		15APR2015	-	Synocrom	HYALURONIC ACID	OTHER DRUGS	Pain-other (AE	2 ml i.a.	17Oct2018	17Oct2018		AE-2
			-	Hyaluronic acid		FOR DISORDERS	no. 02)					
			-			OF THE						
			-			MUSCULO-SKELETA						
			-			L SYSTEM						

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0907	SC	15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	OPHTHALMOLOGICA LS	Pain-other (AE no. 02)	2 ml i.a.	17Oct2018	17Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	THROAT PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	17Oct2018	17Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	NASAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	17Oct2018	17Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	ALL OTHER NON-THERAPEUTIC PRODUCTS	Pain-other (AE no. 02)	2 ml i.a.	17Oct2018	17Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	VASOPROTECTIVES	Pain-other (AE no. 02)	2 ml i.a.	17Oct2018	17Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	17Oct2018	17Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	VASOPROTECTIVES	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	ALL OTHER NON-THERAPEUTIC PRODUCTS	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	THROAT PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	NASAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	OPHTHALMOLOGICA LS	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETA L SYSTEM	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	OTHER DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2
		15APR2015	-	Synocrom Hyaluronic acid	HYALURONIC ACID	PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0907	SC	15APR2015	-	Synocrom	HYALURONIC ACID	OTHER	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2
		15APR2015	-	Hyaluronic acid	HYALURONIC ACID	GYNECOLOGICALS	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2
		15APR2015	-	Synocrom	HYALURONIC ACID	UROLOGICALS	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2
		15APR2015	-	Hyaluronic acid	DEXAMETHASONE	ANTI-ACNE	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Lipotalon	PALMITATE	PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE	CORTICOSTEROIDS	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Lipotalon	PALMITATE	FOR SYSTEMIC	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE	USE	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Lipotalon	PALMITATE	OPHTHALMOLOGICA	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE	OTOLOGICALS	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Lipotalon	PALMITATE	NASAL	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE	PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE	OPHTHALMOLOGICA	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Lipotalon	PALMITATE	L AND	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE	OTOLOGICAL	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE	VASOPROTECTIVES	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Lipotalon	PALMITATE	STOMATOLOGICAL	Pain-other (AE no. 02)	2 ml i.a.	04Oct2018	04Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE	PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE	STOMATOLOGICAL	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Lipotalon	PALMITATE	PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE	VASOPROTECTIVES	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Lipotalon	PALMITATE	OPHTHALMOLOGICA	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE	L AND	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE	OTOLOGICAL	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Lipotalon	PALMITATE	PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE	NASAL	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Lipotalon	PALMITATE	PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE	OTOLOGICALS	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Lipotalon	PALMITATE	OPHTHALMOLOGICA	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE	LS	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0907	SC	15APR2015	-	Lipotalon	DEXAMETHASONE PALMITATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE PALMITATE	ANTI-ACNE PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	10Oct2018	10Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE PALMITATE	ANTI-ACNE PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	17Oct2018	17Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE PALMITATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 02)	2 ml i.a.	17Oct2018	17Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE PALMITATE	OPHTHALMOLOGICA LS	Pain-other (AE no. 02)	2 ml i.a.	17Oct2018	17Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE PALMITATE	OTOLOGICALS	Pain-other (AE no. 02)	2 ml i.a.	17Oct2018	17Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE PALMITATE	NASAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	17Oct2018	17Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE PALMITATE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	17Oct2018	17Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE PALMITATE	VASOPROTECTIVES	Pain-other (AE no. 02)	2 ml i.a.	17Oct2018	17Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE PALMITATE	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	17Oct2018	17Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE PALMITATE	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE PALMITATE	VASOPROTECTIVES	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE PALMITATE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE PALMITATE	NASAL PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE PALMITATE	OTOLOGICALS	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE PALMITATE	OPHTHALMOLOGICA LS	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0907	SC	15APR2015	-	Lipotalon	DEXAMETHASONE PALMITATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2
		15APR2015	-	Lipotalon	DEXAMETHASONE PALMITATE	ANTI-ACNE PREPARATIONS	Pain-other (AE no. 02)	2 ml i.a.	29Oct2018	29Oct2018		AE-2
09/0908	ND basic	07MAY2015	06AUG2015	Certoparin 3000 i.E.	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Anti-Thrombosis	0-0-1	02May2015	06May2015		
		07MAY2015	06AUG2015	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: gastritis prophylaxis	1 x 40 mg	02May2015	10May2015		
		07MAY2015	06AUG2015	Certoparin 3000 i.E.	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Anti Thrombosis	0-0-1	08May2015	16May2015		
		07MAY2015	06AUG2015	Cefazolin	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic treatment	1 x 2 g	07May2015	07May2015		
09/0909	ND plus	12MAY2015	13AUG2015	T-Thyroxin 150 mg	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyreosis (MedHis no. 01)	150mg-0-0	1985	30Sep2015		MH-1
		12MAY2015	13AUG2015	Pantoprazol 40 mg	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Stomach-Protect ion	0-0-1	05May2015	10May2015		
		12MAY2015	13AUG2015	Cefazolin	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic treatment	2 gr.	12May2015	12May2015		
		12MAY2015	13AUG2015	Paracetamol 500 mg	PARACETAMOL	ANALGESICS	Other: cervical spine syndrom (AE no. 03)	2-2-2	14Jul2016	18Jul2016		AE-3
		12MAY2015	13AUG2015	L-Thyroxin 150 ug	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyreodism (MedHis no. 01)	1-0-0	22Jul2016	04Dec2016		MH-1
		12MAY2015	13AUG2015	L-Thyroxin 125 ug	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyreodism (MedHis no. 01)	every second day 125 ug	01Jul2017	25Jul2019		MH-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0909	ND plus	12MAY2015	13AUG2015	Meloxicam 5 mg	MELOXICAM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 05)	1-0-0	19Dec2017	27Dec2017		AE-5
		12MAY2015	13AUG2015	Meloxicam 5 mg	MELOXICAM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 05)	1-0-0	19Dec2017	27Dec2017		AE-5
		12MAY2015	13AUG2015	Meloxicam 5 mg	MELOXICAM	OPHTHALMOLOGICA LS	Pain-other (AE no. 05)	1-0-0	19Dec2017	27Dec2017		AE-5
		12MAY2015	13AUG2015	Euthyrox 125 mg	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyreodism (MedHis no. 01)	1-0-0	20Aug2019		Yes	MH-1
		12MAY2015	13AUG2015	Candesatan 4 mg	CANDESARTAN	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Other: Diastolische Dysfunktion (AE no. 06)	1-0-0	25Oct2019		Yes	AE-6
		12MAY2015	13AUG2015	Bisoprolol 2.5 mg	BISOPROLOL	BETA BLOCKING AGENTS	Other: Hypertension (MedHis no. 02)	2.5mg-0-0	02Nov2014	27Jun2016		MH-2
		12MAY2015	13AUG2015	Pantoprazol 20 mg	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Stomach-Protect ion	1-0-1	11May2015	16May2015		
		12MAY2015	13AUG2015	Certoparin 3000 i.E. sc.	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Anti-thrombosis	0-0-1	05May2015	11May2015		
		12MAY2015	13AUG2015	L-Thyroxin 175 ug	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyroidism (AE no. 01)	1-0-0	01Oct2015	26Jun2016		AE-1
		12MAY2015	13AUG2015	Laxoberal	SODIUM PICOSULFATE	DRUGS FOR CONSTIPATION	Other: Obstipation	12-0-12	06May2015	10May2015		
		12MAY2015	13AUG2015	L-Thyroxin 175 ug	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyreodism (MedHis no. 01)	1-0-0	05Dec2016	30Jun2017		MH-1
		12MAY2015	13AUG2015	L-Thyroxin 150 ug	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyreodism (MedHis no. 01)	every 2nd Day 150 ug	01Jul2017		Yes	MH-1
		12MAY2015	13AUG2015	Novalgin Tabl. 500 mg	METAMIZOLE SODIUM	ANALGESICS	Pain-other (AE no. 05)	as needed	28Dec2017	17Jun2018		AE-5

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0909	ND plus	12MAY2015	13AUG2015	Acetylsalicylic acid 100 mg	ACETYLSALICYLIC ACID	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: AE 06 (AE no. 06)	1-0-0	11Oct2019	23Oct2019		AE-6
		12MAY2015	13AUG2015	Acetylsalicylic acid 100 mg	ACETYLSALICYLIC ACID	ANALGESICS	Other: AE 06 (AE no. 06)	1-0-0	11Oct2019	23Oct2019		AE-6
		12MAY2015	13AUG2015	Acetylsalicylic acid 100 mg	ACETYLSALICYLIC ACID	STOMATOLOGICAL PREPARATIONS	Other: AE 06 (AE no. 06)	1-0-0	11Oct2019	23Oct2019		AE-6
		12MAY2015	13AUG2015	Acetylsalicylic acid 100 mg	ACETYLSALICYLIC ACID	ANTITHROMBOTIC AGENTS	Other: AE 06 (AE no. 06)	1-0-0	11Oct2019	23Oct2019		AE-6
		12MAY2015	13AUG2015	Sabsimplex 5 ml, Simeticon 69.10mg/ml	SIMETICONE	DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	Other: Obstipation	1-0-1	06May2015	10May2015		
		12MAY2015	13AUG2015	Certoparin 3000 i.E. sc.	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Anti-thrombosis	0-0-1	13May2015	25May2015		
		12MAY2015	13AUG2015	Vitamin B12 i.m.	VITAMIN B12 NOS	ANTIANEMIC PREPARATIONS	Other: Anemia (AE no. 04)	every 3 month	01Oct2015	22Dec2016		AE-4
		12MAY2015	13AUG2015	Voltaren Resinat	DICLOFENAC RESINATE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 05)	1-0-1	29Mar2018	09Apr2018		AE-5
		12MAY2015	13AUG2015	Voltaren Resinat	DICLOFENAC RESINATE	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 05)	1-0-1	29Mar2018	09Apr2018		AE-5
		12MAY2015	13AUG2015	Voltaren Resinat	DICLOFENAC RESINATE	OPHTHALMOLOGICALS	Pain-other (AE no. 05)	1-0-1	29Mar2018	09Apr2018		AE-5
		12MAY2015	13AUG2015	Pantoprazol 20 mg	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Stomach protection (AE no. 06)	1-0-0	11Oct2019	23Oct2019		AE-6
		12MAY2015	13AUG2015	Bifiteral Suspension, Lactalose	LACTULOSE	DRUGS FOR CONSTIPATION	Other: Obstipation	20 ml-0-0	10May2015	13May2015		
		12MAY2015	13AUG2015	Bifiteral Suspension, Lactalose	LACTULOSE	BILE AND LIVER THERAPY	Other: Obstipation	20 ml-0-0	10May2015	13May2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0909	ND plus	12MAY2015	13AUG2015	L-Thyroxin 125 ug	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyroidism (AE no. 01)	125mg-0-0	27Jun2016	21Jul2016		AE-1
		12MAY2015	13AUG2015	Euthyrox 137 mg	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyreodism (MedHis no. 01)	1-0-0	26Jul2019	19Aug2019		MH-1
		12MAY2015	13AUG2015	Certoparin 3000 iE. sc.	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophlaxis (AE no. 06)	1-0-0	23Oct2019	24Oct2019		AE-6
09/0910	ND plus	01SEP2015	-	Acetylsalicylic acid	ACETYLSALICYLIC ACID	ANALGESICS	Other: heart related	100 mg 1-0-0	15Feb2010		Yes	
		01SEP2015	-	Acetylsalicylic acid	ACETYLSALICYLIC ACID	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: heart related	100 mg 1-0-0	15Feb2010		Yes	
		01SEP2015	-	Acetylsalicylic acid	ACETYLSALICYLIC ACID	ANTITHROMBOTIC AGENTS	Other: heart related	100 mg 1-0-0	15Feb2010		Yes	
		01SEP2015	-	Acetylsalicylic acid	ACETYLSALICYLIC ACID	STOMATOLOGICAL PREPARATIONS	Other: heart related	100 mg 1-0-0	15Feb2010		Yes	
		01SEP2015	-	Bisprolol	BISOPROLOL	BETA BLOCKING AGENTS	Other: heart-related	5 mg 1/2-0-0	15Feb2010		Yes	
		01SEP2015	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: gastric protection	40 mg 0-0-1	26Aug2015		Yes	
		01SEP2015	-	Certoparin Natrium Fertigspritze	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Antithrombosis	3000 IU sc 0-0-1	26Aug2015	05Sep2015		
		01SEP2015	-	Ramipril	RAMIPRIL	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Other: heart-related	2.5 mg 1-0-0	15Feb2010		Yes	
		01SEP2015	-	Cefazolin 2 gr.	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic treatment	2 gr.-0-0	01Sep2015	01Sep2015		
		01SEP2015	-	Simvastatin	SIMVASTATIN	LIPID MODIFYING AGENTS	Other: heart-related	40 mg 0-0-1	15Feb2010		Yes	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0911	ND plus	19OCT2015	14JAN2016	250 ml NaCl	SODIUM CHLORIDE	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: renal colic (AE no. 01)	250 ml	06May2016	06May2016		AE-1
		19OCT2015	14JAN2016	250 ml NaCl	SODIUM CHLORIDE	STOMATOLOGICAL PREPARATIONS	Other: renal colic (AE no. 01)	250 ml	06May2016	06May2016		AE-1
		19OCT2015	14JAN2016	250 ml NaCl	SODIUM CHLORIDE	DRUGS FOR CONSTIPATION	Other: renal colic (AE no. 01)	250 ml	06May2016	06May2016		AE-1
		19OCT2015	14JAN2016	250 ml NaCl	SODIUM CHLORIDE	MINERAL SUPPLEMENTS	Other: renal colic (AE no. 01)	250 ml	06May2016	06May2016		AE-1
		19OCT2015	14JAN2016	250 ml NaCl	SODIUM CHLORIDE	HOMEOPATHIC PREPARATION	Other: renal colic (AE no. 01)	250 ml	06May2016	06May2016		AE-1
		19OCT2015	14JAN2016	250 ml NaCl	SODIUM CHLORIDE	ALL OTHER NON-THERAPEUTIC PRODUCTS	Other: renal colic (AE no. 01)	250 ml	06May2016	06May2016		AE-1
		19OCT2015	14JAN2016	250 ml NaCl	SODIUM CHLORIDE	ECTOPARASITICID ES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS	Other: renal colic (AE no. 01)	250 ml	06May2016	06May2016		AE-1
		19OCT2015	14JAN2016	250 ml NaCl	SODIUM CHLORIDE	NASAL PREPARATIONS	Other: renal colic (AE no. 01)	250 ml	06May2016	06May2016		AE-1
		19OCT2015	14JAN2016	250 ml NaCl	SODIUM CHLORIDE	OPHTHALMOLOGICA LS	Other: renal colic (AE no. 01)	250 ml	06May2016	06May2016		AE-1
		19OCT2015	14JAN2016	250 ml NaCl	SODIUM CHLORIDE	COUGH AND COLD PREPARATIONS	Other: renal colic (AE no. 01)	250 ml	06May2016	06May2016		AE-1
		19OCT2015	14JAN2016	250 ml NaCl	SODIUM CHLORIDE	OTOLOGICALS	Other: renal colic (AE no. 01)	250 ml	06May2016	06May2016		AE-1
		19OCT2015	14JAN2016	250 ml NaCl	SODIUM CHLORIDE	MEDICATED DRESSINGS	Other: renal colic (AE no. 01)	250 ml	06May2016	06May2016		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing? MH/AE
09/0911	ND plus	19OCT2015	14JAN2016	250 ml NaCl	SODIUM CHLORIDE	PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	Other: renal colic (AE no. 01)	250 ml	06May2016	06May2016	AE-1
		19OCT2015	14JAN2016	Levofloxacin	LEVOFLOXACIN	OPHTHALMOLOGICA LS	Other: renal colic (AE no. 01)	500-0-0 mg	11May2016	17May2016	AE-1
		19OCT2015	14JAN2016	Levofloxacin	LEVOFLOXACIN	OTOLOGICALS	Other: renal colic (AE no. 01)	500-0-0 mg	11May2016	17May2016	AE-1
		19OCT2015	14JAN2016	Levofloxacin	LEVOFLOXACIN	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: renal colic (AE no. 01)	500-0-0 mg	11May2016	17May2016	AE-1
		19OCT2015	14JAN2016	Levofloxacin	LEVOFLOXACIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: renal colic (AE no. 01)	500-0-0 mg	11May2016	17May2016	AE-1
		19OCT2015	14JAN2016	Tilidin 50 mg	VALORON N	ANALGESICS	Pain-other (AE no. 03)	as needed	13Nov2016	23Nov2016	AE-3
		19OCT2015	14JAN2016	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-other (AE no. 04)	2 g	03Sep2017	03Sep2017	AE-4
		19OCT2015	14JAN2016	Diclofenac 75 mg	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 04)	1-0-1	03Sep2017	03Sep2017	AE-4
		19OCT2015	14JAN2016	Diclofenac 75 mg	DICLOFENAC	THROAT PREPARATIONS	Pain-other (AE no. 04)	1-0-1	03Sep2017	03Sep2017	AE-4
		19OCT2015	14JAN2016	Diclofenac 75 mg	DICLOFENAC	OPHTHALMOLOGICA LS	Pain-other (AE no. 04)	1-0-1	03Sep2017	03Sep2017	AE-4
		19OCT2015	14JAN2016	Diclofenac 75 mg	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 04)	1-0-1	03Sep2017	03Sep2017	AE-4
		19OCT2015	14JAN2016	Diclofenac 75 mg	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 04)	1-0-1	03Sep2017	03Sep2017	AE-4
		19OCT2015	14JAN2016	Diclofenac 75 mg	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 04)	1-0-1	03Sep2017	03Sep2017	AE-4

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0911	ND plus	19OCT2015	14JAN2016	Cefuroxim 1.5 g iv	CEFUROXIME	OPHTHALMOLOGICA LS	Other: antibiotic treatment (AE no. 07)	1.5 g	04Oct2017	04Oct2017		AE-7
		19OCT2015	14JAN2016	Cefuroxim 1.5 g iv	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic treatment (AE no. 07)	1.5 g	04Oct2017	04Oct2017		AE-7
		19OCT2015	14JAN2016	Ferrosanol 40 mg	FERROUS GLYCINE SULFATE	ANTIANEMIC PREPARATIONS	Other: AE 11 (AE no. 11)	every 2. Day	02Jan2021		Yes	AE-11
		19OCT2015	14JAN2016	Clindamycin	CLINDAMYCIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Urinary tract Infection (AE no. 10)	3x600mg	23Sep2020	27Sep2020		AE-10
		19OCT2015	14JAN2016	Clindamycin	CLINDAMYCIN	ANTI-ACNE PREPARATIONS	Other: Urinary tract Infection (AE no. 10)	3x600mg	23Sep2020	27Sep2020		AE-10
		19OCT2015	14JAN2016	Clindamycin	CLINDAMYCIN	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: Urinary tract Infection (AE no. 10)	3x600mg	23Sep2020	27Sep2020		AE-10
		19OCT2015	14JAN2016	Cefazolin 2 gr.	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic treatment	0-1-0	19Oct2015	19Oct2015		
		19OCT2015	14JAN2016	Vomex A	DIMENHYDRINATE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: renal colic (AE no. 01)	62 mg/10 ml	06May2016	06May2016		AE-1
		19OCT2015	14JAN2016	Vomex A	DIMENHYDRINATE	OTHER NERVOUS SYSTEM DRUGS	Other: renal colic (AE no. 01)	62 mg/10 ml	06May2016	06May2016		AE-1
		19OCT2015	14JAN2016	Vomex A	DIMENHYDRINATE	ANTIEMETICS AND ANTINAUSEANTS	Other: renal colic (AE no. 01)	62 mg/10 ml	06May2016	06May2016		AE-1
		19OCT2015	14JAN2016	Ibuflam 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 03)	1-0-1	13Nov2016	16Nov2016		AE-3

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0911	ND plus	19OCT2015	14JAN2016	Ibuflam 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 03)	1-0-1	13Nov2016	16Nov2016		AE-3
		19OCT2015	14JAN2016	Ibuflam 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 03)	1-0-1	13Nov2016	16Nov2016		AE-3
		19OCT2015	14JAN2016	Ibuflam 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 03)	1-0-1	13Nov2016	16Nov2016		AE-3
		19OCT2015	14JAN2016	Ibuflam 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 03)	1-0-1	13Nov2016	16Nov2016		AE-3
		19OCT2015	14JAN2016	Buscupan 1 Amp iv	HYOSCINE BUTYLBROMIDE	DRUGS FOR FUNCTIONAL GASTROINTESTINA L DISORDERS	Pain-other (AE no. 04)	7.5 mg	03Sep2017	03Sep2017		AE-4
		19OCT2015	14JAN2016	Novalgin 1 g	METAMIZOLE SODIUM	ANALGESICS	Pain-other (AE no. 04)	1-1-1	03Sep2017	03Sep2017		AE-4
		19OCT2015	14JAN2016	Novalgin Tabl. 500 mg	METAMIZOLE SODIUM	ANALGESICS	Pain-other (AE no. 06)	2-2-2-2	04Oct2017	17Oct2017		AE-6
		19OCT2015	14JAN2016	Jodid 200 um	POTASSIUM IODIDE	ALL OTHER THERAPEUTIC PRODUCTS	Other: AE 11 (AE no. 11)	1-0-0	02Jan2021		Yes	AE-11
		19OCT2015	14JAN2016	Jodid 200 um	POTASSIUM IODIDE	OPHTHALMOLOGICA LS	Other: AE 11 (AE no. 11)	1-0-0	02Jan2021		Yes	AE-11
		19OCT2015	14JAN2016	Jodid 200 um	POTASSIUM IODIDE	COUGH AND COLD PREPARATIONS	Other: AE 11 (AE no. 11)	1-0-0	02Jan2021		Yes	AE-11
		19OCT2015	14JAN2016	Jodid 200 um	POTASSIUM IODIDE	THYROID THERAPY	Other: AE 11 (AE no. 11)	1-0-0	02Jan2021		Yes	AE-11
		19OCT2015	14JAN2016	Cotrimazol suppository	CLOTRIMAZOLE	STOMATOLOGICAL PREPARATIONS	Other: vaginal mycosis (AE no. 09)	0-0-0-1	23Sep2020	27Sep2020		AE-9
		19OCT2015	14JAN2016	Cotrimazol suppository	CLOTRIMAZOLE	ANTIPROTOZOALS	Other: vaginal mycosis (AE no. 09)	0-0-0-1	23Sep2020	27Sep2020		AE-9
		19OCT2015	14JAN2016	Cotrimazol suppository	CLOTRIMAZOLE	OPHTHALMOLOGICA LS	Other: vaginal mycosis (AE no. 09)	0-0-0-1	23Sep2020	27Sep2020		AE-9
		19OCT2015	14JAN2016	Cotrimazol suppository	CLOTRIMAZOLE	OTOLOGICALS	Other: vaginal mycosis (AE no. 09)	0-0-0-1	23Sep2020	27Sep2020		AE-9

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0911	ND plus	19OCT2015	14JAN2016	Cotrimazol suppository	CLOTRIMAZOLE	ANTIFUNGALS FOR DERMATOLOGICAL USE	Other: vaginal mycosis (AE no. 09)	0-0-0-1	23Sep2020	27Sep2020		AE-9
		19OCT2015	14JAN2016	Cotrimazol suppository	CLOTRIMAZOLE	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: vaginal mycosis (AE no. 09)	0-0-0-1	23Sep2020	27Sep2020		AE-9
		19OCT2015	14JAN2016	Pantoprazol 40 mg	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Gastric protection	0-0-0-1	15Dec2014	18Oct2015		
		19OCT2015	14JAN2016	Certoparin 3000 i.E. sc.	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Anti Thrombosis	0-0-1	18Oct2015	18Oct2015		
		19OCT2015	14JAN2016	Novalgin 2.5 gr	METAMIZOLE SODIUM	ANALGESICS	Other: renal colic (AE no. 01)	2.5 gr/5 ml	06May2016	06May2016		AE-1
		19OCT2015	14JAN2016	Diclac Dispers 50 mg	DICLOFENAC	THROAT PREPARATIONS	Pain-other (AE no. 03)	1-0-1	17Nov2016	23Nov2016		AE-3
		19OCT2015	14JAN2016	Diclac Dispers 50 mg	DICLOFENAC	OPHTHALMOLOGICA LS	Pain-other (AE no. 03)	1-0-1	17Nov2016	23Nov2016		AE-3
		19OCT2015	14JAN2016	Diclac Dispers 50 mg	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 03)	1-0-1	17Nov2016	23Nov2016		AE-3
		19OCT2015	14JAN2016	Diclac Dispers 50 mg	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 03)	1-0-1	17Nov2016	23Nov2016		AE-3
		19OCT2015	14JAN2016	Diclac Dispers 50 mg	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 03)	1-0-1	17Nov2016	23Nov2016		AE-3
		19OCT2015	14JAN2016	Diclac Dispers 50 mg	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 03)	1-0-1	17Nov2016	23Nov2016		AE-3
		19OCT2015	14JAN2016	Piritramid	PIRITRAMIDE	ANALGESICS	Pain-other (AE no. 04)	7.5 mg	03Sep2017	03Sep2017		AE-4
		19OCT2015	14JAN2016	Tamsulosin 0.4 mg	TAMSULOSIN	UROLOGICALS	Other: Diureticum (renal colic) (AE no. 04)	0-0-1	03Sep2017	03Sep2017		AE-4

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0911	ND plus	19OCT2015	14JAN2016	Targin 10/5	TARGIN	ANALGESICS	Pain-other (AE no. 07)	1-0-1	04Oct2017	17Oct2017		AE-7
		19OCT2015	14JAN2016	Targin 10/5	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-other (AE no. 07)	1-0-1	04Oct2017	17Oct2017		AE-7
		19OCT2015	14JAN2016	Iluprophen 400 mg	IBUPROFEN	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	Pain-other: AE 11 (AE no. 11)	1-1-1	02Jan2021	05Jan2021		AE-11
		19OCT2015	14JAN2016	Iluprophen 400 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other: AE 11 (AE no. 11)	1-1-1	02Jan2021	05Jan2021		AE-11
		19OCT2015	14JAN2016	Iluprophen 400 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other: AE 11 (AE no. 11)	1-1-1	02Jan2021	05Jan2021		AE-11
		19OCT2015	14JAN2016	Iluprophen 400 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-other: AE 11 (AE no. 11)	1-1-1	02Jan2021	05Jan2021		AE-11
		19OCT2015	14JAN2016	Iluprophen 400 mg	IBUPROFEN	CARDIAC THERAPY	Pain-other: AE 11 (AE no. 11)	1-1-1	02Jan2021	05Jan2021		AE-11
		19OCT2015	14JAN2016	Cotrimazol Creme	CLOTRIMAZOLE	ANTIFUNGALS FOR DERMATOLOGICAL USE	Other: vaginal mycosis (AE no. 09)	1-1-1	23Sep2020	27Sep2020		AE-9
		19OCT2015	14JAN2016	Cotrimazol Creme	CLOTRIMAZOLE	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: vaginal mycosis (AE no. 09)	1-1-1	23Sep2020	27Sep2020		AE-9
		19OCT2015	14JAN2016	Cotrimazol Creme	CLOTRIMAZOLE	OPHTHALMOLOGICALS	Other: vaginal mycosis (AE no. 09)	1-1-1	23Sep2020	27Sep2020		AE-9
		19OCT2015	14JAN2016	Cotrimazol Creme	CLOTRIMAZOLE	OTOLOGICALS	Other: vaginal mycosis (AE no. 09)	1-1-1	23Sep2020	27Sep2020		AE-9
		19OCT2015	14JAN2016	Cotrimazol Creme	CLOTRIMAZOLE	ANTIPROTOZOALS	Other: vaginal mycosis (AE no. 09)	1-1-1	23Sep2020	27Sep2020		AE-9
		19OCT2015	14JAN2016	Cotrimazol Creme	CLOTRIMAZOLE	STOMATOLOGICAL PREPARATIONS	Other: vaginal mycosis (AE no. 09)	1-1-1	23Sep2020	27Sep2020		AE-9
		19OCT2015	14JAN2016	Certoparin 3000 i.E. sc	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Anti-thrombosis	0-0-1	20Oct2015	22Oct2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0911	ND plus	19OCT2015	14JAN2016	Cefuroxin	CEFUROXIME SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: renal colic (AE no. 01)	500mg-0-500mg	08May2016	10May2016		AE-1
		19OCT2015	14JAN2016	Cefuroxin	CEFUROXIME SODIUM	OPHTHALMOLOGICA LS	Other: renal colic (AE no. 01)	500mg-0-500mg	08May2016	10May2016		AE-1
		19OCT2015	14JAN2016	Dexa Allvoran 4 mg	DEXAMETHASONE SODIUM PHOSPHATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 03)	1ml-0-0	14Nov2016	17Nov2016		AE-3
		19OCT2015	14JAN2016	Dexa Allvoran 4 mg	DEXAMETHASONE SODIUM PHOSPHATE	ANTI-ACNE PREPARATIONS	Pain-other (AE no. 03)	1ml-0-0	14Nov2016	17Nov2016		AE-3
		19OCT2015	14JAN2016	Dexa Allvoran 4 mg	DEXAMETHASONE SODIUM PHOSPHATE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 03)	1ml-0-0	14Nov2016	17Nov2016		AE-3
		19OCT2015	14JAN2016	Dexa Allvoran 4 mg	DEXAMETHASONE SODIUM PHOSPHATE	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 03)	1ml-0-0	14Nov2016	17Nov2016		AE-3
		19OCT2015	14JAN2016	Dexa Allvoran 4 mg	DEXAMETHASONE SODIUM PHOSPHATE	VASOPROTECTIVES	Pain-other (AE no. 03)	1ml-0-0	14Nov2016	17Nov2016		AE-3
		19OCT2015	14JAN2016	Dexa Allvoran 4 mg	DEXAMETHASONE SODIUM PHOSPHATE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Pain-other (AE no. 03)	1ml-0-0	14Nov2016	17Nov2016		AE-3
		19OCT2015	14JAN2016	Dexa Allvoran 4 mg	DEXAMETHASONE SODIUM PHOSPHATE	OPHTHALMOLOGICA LS	Pain-other (AE no. 03)	1ml-0-0	14Nov2016	17Nov2016		AE-3
		19OCT2015	14JAN2016	Dexa Allvoran 4 mg	DEXAMETHASONE SODIUM PHOSPHATE	OTOLOGICALS	Pain-other (AE no. 03)	1ml-0-0	14Nov2016	17Nov2016		AE-3
		19OCT2015	14JAN2016	Dexa Allvoran 4 mg	DEXAMETHASONE SODIUM PHOSPHATE	NASAL PREPARATIONS	Pain-other (AE no. 03)	1ml-0-0	14Nov2016	17Nov2016		AE-3
		19OCT2015	14JAN2016	Pantropazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Stomach prophylaxis (AE no. 04)	40 mg-0-0	03Sep2017	03Sep2017		AE-4

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0911	ND plus	19OCT2015	14JAN2016	Mono-Embolex 3000 i.E.	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Anti Thrombose (AE no. 04)	0-0-1	03Sep2017	03Sep2017		AE-4
		19OCT2015	14JAN2016	Ciprofloxacin 500 mg Tabl.	CIPROFLOXACIN	OPHTHALMOLOGICA LS	Other: antibiotic treatment (AE no. 06)	1-0-1	04Oct2017	16Oct2017		AE-6
		19OCT2015	14JAN2016	Ciprofloxacin 500 mg Tabl.	CIPROFLOXACIN	OTOLOGICALS	Other: antibiotic treatment (AE no. 06)	1-0-1	04Oct2017	16Oct2017		AE-6
		19OCT2015	14JAN2016	Ciprofloxacin 500 mg Tabl.	CIPROFLOXACIN	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: antibiotic treatment (AE no. 06)	1-0-1	04Oct2017	16Oct2017		AE-6
		19OCT2015	14JAN2016	Ciprofloxacin 500 mg Tabl.	CIPROFLOXACIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic treatment (AE no. 06)	1-0-1	04Oct2017	16Oct2017		AE-6
		19OCT2015	14JAN2016	Ciprofloxacin 500 mg Tabl.	CIPROFLOXACIN	ANTIBIOTICS AND CHEMOTHERAPEUTI CS FOR DERMATOLOGICAL USE	Other: antibiotic treatment (AE no. 06)	1-0-1	04Oct2017	16Oct2017		AE-6
		19OCT2015	14JAN2016	Ciprofloxacin 500 mg Tabl.	CIPROFLOXACIN	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: antibiotic treatment (AE no. 06)	1-0-1	04Oct2017	16Oct2017		AE-6
		19OCT2015	14JAN2016	Iluprophen 400 mg	IBUPROFEN	CARDIAC THERAPY	Pain-other: AE 11 (AE no. 11)	1-0-1	06Jan2021	Jan2021		AE-11
		19OCT2015	14JAN2016	Iluprophen 400 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-other: AE 11 (AE no. 11)	1-0-1	06Jan2021	Jan2021		AE-11
		19OCT2015	14JAN2016	Iluprophen 400 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other: AE 11 (AE no. 11)	1-0-1	06Jan2021	Jan2021		AE-11
		19OCT2015	14JAN2016	Iluprophen 400 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other: AE 11 (AE no. 11)	1-0-1	06Jan2021	Jan2021		AE-11

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0911	ND plus	19OCT2015	14JAN2016	Iluprophen 400 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other: AE 11 (AE no. 11)	1-0-1	06Jan2021	Jan2021		AE-11
		19OCT2015	14JAN2016	Folic acid	FOLIC ACID	ANTIANEMIC PREPARATIONS	Other: pregnancy	400 ug	06Jan2020	31Dec2020		
		19OCT2015	14JAN2016	Folic acid	FOLIC ACID	DIAGNOSTIC AGENTS	Other: pregnancy	400 ug	06Jan2020	31Dec2020		
		19OCT2015	14JAN2016	Folic acid	FOLIC ACID	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: pregnancy	400 ug	06Jan2020	31Dec2020		
09/0912	ND plus	20OCT2015	21JAN2016	Novalgin Tabl. 500 mg	METAMIZOLE SODIUM	ANALGESICS	Pain-other (AE no. 02)	1-0-1	13Jul2018	22Jul2018		AE-2
		20OCT2015	21JAN2016	Certoparin 3000 i.E. sc.	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Antithrombose	0-0-1	21Oct2015	04Nov2015		
		20OCT2015	21JAN2016	Spasmolyt 30 mg Tabl.	TROSPIUM CHLORIDE	UROLOGICALS	Other: irritation bladder (AE no. 03)	1-1-1	07Aug2018	30Sep2018		AE-3
		20OCT2015	21JAN2016	Spasmolyt 30 mg Tabl.	TROSPIUM CHLORIDE	DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	Other: irritation bladder (AE no. 03)	1-1-1	07Aug2018	30Sep2018		AE-3
		20OCT2015	21JAN2016	Spasmolyt Tabl. 30 mg	TROSPIUM CHLORIDE	DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	Other: irritation bladder (AE no. 03)	2-1-2	01Oct2018	06Nov2019		AE-3
		20OCT2015	21JAN2016	Spasmolyt Tabl. 30 mg	TROSPIUM CHLORIDE	UROLOGICALS	Other: irritation bladder (AE no. 03)	2-1-2	01Oct2018	06Nov2019		AE-3
		20OCT2015	21JAN2016	Cefazolin 2 g	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic treatment	0-1-0	20Oct2015	20Oct2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0912	ND plus	20OCT2015	21JAN2016	Baldrian Dispers	VALERIANA OFFICINALIS ROOT	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	Other: insomnia prophylaxis	0-0-0-1	03Dec2015	24Dec2015		
		20OCT2015	21JAN2016	Spasmolyt Tabl. 30 mg	TROSPIUM CHLORIDE	UROLOGICALS	Other: irritation bladder (AE no. 03)	2-1-1	07Nov2019		Yes	AE-3
		20OCT2015	21JAN2016	Spasmolyt Tabl. 30 mg	TROSPIUM CHLORIDE	DRUGS FOR FUNCTIONAL GASTROINTESTINA L DISORDERS	Other: irritation bladder (AE no. 03)	2-1-1	07Nov2019		Yes	AE-3
09/0913	ND basic	30NOV2015	18FEB2016	Certoparin Na 3000 i.E. sc.	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Anti-Thrombose	0-0-1	29Nov2015	29Nov2015		
		30NOV2015	18FEB2016	Ibuprophen 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: Parotid gland inflammation (AE no. 02)	1-0-1	12Jul2016	17Jul2016		AE-2
		30NOV2015	18FEB2016	Ibuprophen 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Other: Parotid gland inflammation (AE no. 02)	1-0-1	12Jul2016	17Jul2016		AE-2
		30NOV2015	18FEB2016	Ibuprophen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: Parotid gland inflammation (AE no. 02)	1-0-1	12Jul2016	17Jul2016		AE-2
		30NOV2015	18FEB2016	Ibuprophen 600 mg	IBUPROFEN	CARDIAC THERAPY	Other: Parotid gland inflammation (AE no. 02)	1-0-1	12Jul2016	17Jul2016		AE-2
		30NOV2015	18FEB2016	Ibuprophen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Other: Parotid gland inflammation (AE no. 02)	1-0-1	12Jul2016	17Jul2016		AE-2
		30NOV2015	18FEB2016	Ortoton 750 mg	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-other (AE no. 03)	1-1-1	24Jan2017	24Jan2017		AE-3

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0913	ND basic	30NOV2015	18FEB2016	Sertralín 25 mg	SERTRALINE	PSYCHOANALEPTIC S	Other: Depressive mode (AE no. 04)	1-0-0	27Nov2017	UNK		AE-4
		30NOV2015	18FEB2016	Certoparin Na 3000 i.E. sc.	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Anti-Thrombose	0-0-1	01Dec2015	16Dec2015		
		30NOV2015	18FEB2016	Cefazolin 2 g	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic treatment	0-1-0	30Nov2015	30Nov2015		
		30NOV2015	18FEB2016	Celebrex 100 mg	CELECOXIB	ANTINEOPLASTIC AGENTS	Pain-other (AE no. 03)	1-0-1	25Jan2017	27Jan2017		AE-3
		30NOV2015	18FEB2016	Celebrex 100 mg	CELECOXIB	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 03)	1-0-1	25Jan2017	27Jan2017		AE-3
09/0914	SC	06JAN2016	-	Certoparin 3000 i.E. s.c.	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Anti-thrombosis	0-0-1	07Jan2016	10Jan2016		
		06JAN2016	-	Innohep 3500 0.35 sc.	TINZAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Antithrombose	0-0-1	11Jan2016	28Jan2016		
		06JAN2016	-	Amoclav 500 mg	AUGMENTIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: sinusitis frontalis (AE no. 01)	500-0-500	19Apr2016	26Apr2016		AE-1
					/00756801/							
		06JAN2016	-	Prednisolon 100 mg	PREDNISOLONE	OPHTHALMOLOGICA LS	Other: Sinusitis frontalis (AE no. 01)	100 mg 0-0	20May2016	21May2016		AE-1
		06JAN2016	-	Prednisolon 100 mg	PREDNISOLONE	OTOLOGICALS	Other: Sinusitis frontalis (AE no. 01)	100 mg 0-0	20May2016	21May2016		AE-1
		06JAN2016	-	Prednisolon 100 mg	PREDNISOLONE	NASAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	100 mg 0-0	20May2016	21May2016		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0914	SC	06JAN2016	-	Prednisolon 100 mg	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	100 mg 0-0	20May2016	21May2016		AE-1
		06JAN2016	-	Prednisolon 100 mg	PREDNISOLONE	VASOPROTECTIVES	Other: Sinusitis frontalis (AE no. 01)	100 mg 0-0	20May2016	21May2016		AE-1
		06JAN2016	-	Prednisolon 100 mg	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: Sinusitis frontalis (AE no. 01)	100 mg 0-0	20May2016	21May2016		AE-1
		06JAN2016	-	Prednisolon 100 mg	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	100 mg 0-0	20May2016	21May2016		AE-1
		06JAN2016	-	Prednisolon 100 mg	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	100 mg 0-0	20May2016	21May2016		AE-1
		06JAN2016	-	Prednisolon 100 mg	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Sinusitis frontalis (AE no. 01)	100 mg 0-0	20May2016	21May2016		AE-1
		06JAN2016	-	Prednisolon 20 mg	PREDNISOLONE	OPHTHALMOLOGICA LS	Other: Sinusitis frontalis (AE no. 01)	20-0-0	28May2016	29May2016		AE-1
		06JAN2016	-	Prednisolon 20 mg	PREDNISOLONE	OTOLOGICALS	Other: Sinusitis frontalis (AE no. 01)	20-0-0	28May2016	29May2016		AE-1
		06JAN2016	-	Prednisolon 20 mg	PREDNISOLONE	NASAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	20-0-0	28May2016	29May2016		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0914	SC	06JAN2016	-	Prednisolon 20 mg	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	20-0-0	28May2016	29May2016		AE-1
		06JAN2016	-	Prednisolon 20 mg	PREDNISOLONE	VASOPROTECTIVES	Other: Sinusitis frontalis (AE no. 01)	20-0-0	28May2016	29May2016		AE-1
		06JAN2016	-	Prednisolon 20 mg	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: Sinusitis frontalis (AE no. 01)	20-0-0	28May2016	29May2016		AE-1
		06JAN2016	-	Prednisolon 20 mg	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	20-0-0	28May2016	29May2016		AE-1
		06JAN2016	-	Prednisolon 20 mg	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	20-0-0	28May2016	29May2016		AE-1
		06JAN2016	-	Prednisolon 20 mg	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Sinusitis frontalis (AE no. 01)	20-0-0	28May2016	29May2016		AE-1
		06JAN2016	-	Cefazolin 2 g	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic treatment	0-1-0	06Jan2016	06Jan2016		
		06JAN2016	-	Prednisolon 200 mg	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Sinusitis frontalis (AE no. 01)	200-0-0	13May2016	15May2016		AE-1
		06JAN2016	-	Prednisolon 200 mg	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	200-0-0	13May2016	15May2016		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0914	SC	06JAN2016	-	Prednisolon 200 mg	PREDNISOLONE	ANTIDIARRHEALS, ANTIDIARRHEALS, ANTIDIARRHEALS, ANTIDIARRHEALS, ANTIDIARRHEALS, ANTIDIARRHEALS, ANTIDIARRHEALS, ANTIDIARRHEALS, ANTIDIARRHEALS	Other: Sinusitis frontalis (AE no. 01)	200-0-0	13May2016	15May2016		AE-1
		06JAN2016	-	Prednisolon 200 mg	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	200-0-0	13May2016	15May2016		AE-1
		06JAN2016	-	Prednisolon 200 mg	PREDNISOLONE	VASOPROTECTIVES	Other: Sinusitis frontalis (AE no. 01)	200-0-0	13May2016	15May2016		AE-1
		06JAN2016	-	Prednisolon 200 mg	PREDNISOLONE	OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	200-0-0	13May2016	15May2016		AE-1
		06JAN2016	-	Prednisolon 200 mg	PREDNISOLONE	NASAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	200-0-0	13May2016	15May2016		AE-1
		06JAN2016	-	Prednisolon 200 mg	PREDNISOLONE	OPHTHALMOLOGICALS	Other: Sinusitis frontalis (AE no. 01)	200-0-0	13May2016	15May2016		AE-1
		06JAN2016	-	Prednisolon 200 mg	PREDNISOLONE	OTOLOGICALS	Other: Sinusitis frontalis (AE no. 01)	200-0-0	13May2016	15May2016		AE-1
		06JAN2016	-	Prednisolon 80 mg	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Sinusitis frontalis (AE no. 01)	80-0-0	22May2016	23May2016		AE-1
		06JAN2016	-	Prednisolon 80 mg	PREDNISOLONE	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	80-0-0	22May2016	23May2016		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0914	SC	06JAN2016	-	Prednisolon 80 mg	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	80-0-0	22May2016	23May2016		AE-1
		06JAN2016	-	Prednisolon 80 mg	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: Sinusitis frontalis (AE no. 01)	80-0-0	22May2016	23May2016		AE-1
		06JAN2016	-	Prednisolon 80 mg	PREDNISOLONE	VASOPROTECTIVES	Other: Sinusitis frontalis (AE no. 01)	80-0-0	22May2016	23May2016		AE-1
		06JAN2016	-	Prednisolon 80 mg	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	80-0-0	22May2016	23May2016		AE-1
		06JAN2016	-	Prednisolon 80 mg	PREDNISOLONE	NASAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	80-0-0	22May2016	23May2016		AE-1
		06JAN2016	-	Prednisolon 80 mg	PREDNISOLONE	OPHTHALMOLOGICA LS	Other: Sinusitis frontalis (AE no. 01)	80-0-0	22May2016	23May2016		AE-1
		06JAN2016	-	Prednisolon 80 mg	PREDNISOLONE	OTOLOGICALS	Other: Sinusitis frontalis (AE no. 01)	80-0-0	22May2016	23May2016		AE-1
		06JAN2016	-	Prednisolon 10 mg	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Sinusitis frontalis (AE no. 01)	10 mg 0-0	30May2016	31May2016		AE-1
		06JAN2016	-	Prednisolon 10 mg	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	10 mg 0-0	30May2016	31May2016		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0914	SC	06JAN2016	-	Prednisolon 10 mg	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: Sinusitis frontalis (AE no. 01)	10 mg 0-0	30May2016	31May2016		AE-1
		06JAN2016	-	Prednisolon 10 mg	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	10 mg 0-0	30May2016	31May2016		AE-1
		06JAN2016	-	Prednisolon 10 mg	PREDNISOLONE	VASOPROTECTIVES	Other: Sinusitis frontalis (AE no. 01)	10 mg 0-0	30May2016	31May2016		AE-1
		06JAN2016	-	Prednisolon 10 mg	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	10 mg 0-0	30May2016	31May2016		AE-1
		06JAN2016	-	Prednisolon 10 mg	PREDNISOLONE	NASAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	10 mg 0-0	30May2016	31May2016		AE-1
		06JAN2016	-	Prednisolon 10 mg	PREDNISOLONE	OPHTHALMOLOGICA LS	Other: Sinusitis frontalis (AE no. 01)	10 mg 0-0	30May2016	31May2016		AE-1
		06JAN2016	-	Prednisolon 10 mg	PREDNISOLONE	OTOLOGICALS	Other: Sinusitis frontalis (AE no. 01)	10 mg 0-0	30May2016	31May2016		AE-1
		06JAN2016	-	Omeprazole 20 mg	OMEPRAZOLE	DRUGS FOR ACID RELATED DISORDERS	Other: Stomach protection	1-0-0	21Jan2016	22Feb2016		
		06JAN2016	-	Prednisolon 150 mg	PREDNISOLONE	OPHTHALMOLOGICA LS	Other: Sinusitis frontalis (AE no. 01)	150-0-0	16May2016	17May2016		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0914	SC	06JAN2016	-	Prednisolon 150 mg	PREDNISOLONE	OTOLOGICALS	Other: Sinusitis frontalis (AE no. 01)	150-0-0	16May2016	17May2016		AE-1
		06JAN2016	-	Prednisolon 150 mg	PREDNISOLONE	NASAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	150-0-0	16May2016	17May2016		AE-1
		06JAN2016	-	Prednisolon 150 mg	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	150-0-0	16May2016	17May2016		AE-1
		06JAN2016	-	Prednisolon 150 mg	PREDNISOLONE	VASOPROTECTIVES	Other: Sinusitis frontalis (AE no. 01)	150-0-0	16May2016	17May2016		AE-1
		06JAN2016	-	Prednisolon 150 mg	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	150-0-0	16May2016	17May2016		AE-1
		06JAN2016	-	Prednisolon 150 mg	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: Sinusitis frontalis (AE no. 01)	150-0-0	16May2016	17May2016		AE-1
		06JAN2016	-	Prednisolon 150 mg	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	150-0-0	16May2016	17May2016		AE-1
		06JAN2016	-	Prednisolon 150 mg	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Sinusitis frontalis (AE no. 01)	150-0-0	16May2016	17May2016		AE-1
		06JAN2016	-	Prednisolon 60 mg	PREDNISOLONE	OPHTHALMOLOGICA LS	Other: Sinusitis frontalis (AE no. 01)	60-0-0	24May2016	25May2016		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0914	SC	06JAN2016	-	Prednisolon 60 mg	PREDNISOLONE	OTOLOGICALS	Other: Sinusitis frontalis (AE no. 01)	60-0-0	24May2016	25May2016		AE-1
		06JAN2016	-	Prednisolon 60 mg	PREDNISOLONE	NASAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	60-0-0	24May2016	25May2016		AE-1
		06JAN2016	-	Prednisolon 60 mg	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	60-0-0	24May2016	25May2016		AE-1
		06JAN2016	-	Prednisolon 60 mg	PREDNISOLONE	VASOPROTECTIVES	Other: Sinusitis frontalis (AE no. 01)	60-0-0	24May2016	25May2016		AE-1
		06JAN2016	-	Prednisolon 60 mg	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	60-0-0	24May2016	25May2016		AE-1
		06JAN2016	-	Prednisolon 60 mg	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: Sinusitis frontalis (AE no. 01)	60-0-0	24May2016	25May2016		AE-1
		06JAN2016	-	Prednisolon 60 mg	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	60-0-0	24May2016	25May2016		AE-1
		06JAN2016	-	Prednisolon 60 mg	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Sinusitis frontalis (AE no. 01)	60-0-0	24May2016	25May2016		AE-1
		06JAN2016	-	Prednisolon 5 mg	PREDNISOLONE	OPHTHALMOLOGICA LS	Other: Sinusitis frontalis (AE no. 01)	5-0-0	01Jun2016	01Jun2016		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0914	SC	06JAN2016	-	Prednisolon 5 mg	PREDNISOLONE	OTOLOGICALS	Other: Sinusitis frontalis (AE no. 01)	5-0-0	01Jun2016	01Jun2016		AE-1
		06JAN2016	-	Prednisolon 5 mg	PREDNISOLONE	NASAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	5-0-0	01Jun2016	01Jun2016		AE-1
		06JAN2016	-	Prednisolon 5 mg	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	5-0-0	01Jun2016	01Jun2016		AE-1
		06JAN2016	-	Prednisolon 5 mg	PREDNISOLONE	VASOPROTECTIVES	Other: Sinusitis frontalis (AE no. 01)	5-0-0	01Jun2016	01Jun2016		AE-1
		06JAN2016	-	Prednisolon 5 mg	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: Sinusitis frontalis (AE no. 01)	5-0-0	01Jun2016	01Jun2016		AE-1
		06JAN2016	-	Prednisolon 5 mg	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	5-0-0	01Jun2016	01Jun2016		AE-1
		06JAN2016	-	Prednisolon 5 mg	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	5-0-0	01Jun2016	01Jun2016		AE-1
		06JAN2016	-	Prednisolon 5 mg	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Sinusitis frontalis (AE no. 01)	5-0-0	01Jun2016	01Jun2016		AE-1
		06JAN2016	-	Prednisolon 125 mg	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Sinusitis frontalis (AE no. 01)	125-0-0	18May2016	19May2016		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0914	SC	06JAN2016	-	Prednisolon 125 mg	PREDNISOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	125-0-0	18May2016	19May2016		AE-1
		06JAN2016	-	Prednisolon 125 mg	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: Sinusitis frontalis (AE no. 01)	125-0-0	18May2016	19May2016		AE-1
		06JAN2016	-	Prednisolon 125 mg	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	125-0-0	18May2016	19May2016		AE-1
		06JAN2016	-	Prednisolon 125 mg	PREDNISOLONE	VASOPROTECTIVES	Other: Sinusitis frontalis (AE no. 01)	125-0-0	18May2016	19May2016		AE-1
		06JAN2016	-	Prednisolon 125 mg	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	125-0-0	18May2016	19May2016		AE-1
		06JAN2016	-	Prednisolon 125 mg	PREDNISOLONE	NASAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	125-0-0	18May2016	19May2016		AE-1
		06JAN2016	-	Prednisolon 125 mg	PREDNISOLONE	OPHTHALMOLOGICA LS	Other: Sinusitis frontalis (AE no. 01)	125-0-0	18May2016	19May2016		AE-1
		06JAN2016	-	Prednisolon 125 mg	PREDNISOLONE	OTOLOGICALS	Other: Sinusitis frontalis (AE no. 01)	125-0-0	18May2016	19May2016		AE-1
		06JAN2016	-	Prednisolon 40 mg	PREDNISOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: Sinusitis frontalis (AE no. 01)	40-0-0	26May2016	27May2016		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0914	SC	06JAN2016	-	Prednisolon 40 mg	PREDNISOLONE	CORTICOSTEROIDS	Other: Sinusitis frontalis (AE no. 01)	40-0-0	26May2016	27May2016		AE-1
		06JAN2016	-	Prednisolon 40 mg	PREDNISOLONE	DERMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	40-0-0	26May2016	27May2016		AE-1
		06JAN2016	-	Prednisolon 40 mg	PREDNISOLONE	STOMATOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	40-0-0	26May2016	27May2016		AE-1
		06JAN2016	-	Prednisolon 40 mg	PREDNISOLONE	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATOR Y/ANTIINFECTIVE AGENTS	Other: Sinusitis frontalis (AE no. 01)	40-0-0	26May2016	27May2016		AE-1
		06JAN2016	-	Prednisolon 40 mg	PREDNISOLONE	VASOPROTECTIVES	Other: Sinusitis frontalis (AE no. 01)	40-0-0	26May2016	27May2016		AE-1
		06JAN2016	-	Prednisolon 40 mg	PREDNISOLONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	40-0-0	26May2016	27May2016		AE-1
		06JAN2016	-	Prednisolon 40 mg	PREDNISOLONE	NASAL PREPARATIONS	Other: Sinusitis frontalis (AE no. 01)	40-0-0	26May2016	27May2016		AE-1
		06JAN2016	-	Prednisolon 40 mg	PREDNISOLONE	OPHTHALMOLOGICA LS	Other: Sinusitis frontalis (AE no. 01)	40-0-0	26May2016	27May2016		AE-1
09/0915	ND basic	06JAN2016	24MAR2016	Certoparin Na 3000 i.E. sc.	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Anti-thrombosis	0-0-1	07Jan2016	17Jan2016		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0915	ND basic	06JAN2016	24MAR2016	Ibuprophen 800 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 02)	3x800 mg	12Dec2016	28Dec2016		AE-2
		06JAN2016	24MAR2016	Ibuprophen 800 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 02)	3x800 mg	12Dec2016	28Dec2016		AE-2
		06JAN2016	24MAR2016	Ibuprophen 800 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 02)	3x800 mg	12Dec2016	28Dec2016		AE-2
		06JAN2016	24MAR2016	Ibuprophen 800 mg	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 02)	3x800 mg	12Dec2016	28Dec2016		AE-2
		06JAN2016	24MAR2016	Ibuprophen 800 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 02)	3x800 mg	12Dec2016	28Dec2016		AE-2
		06JAN2016	24MAR2016	Ibuprophen 400 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 03)	1-0-1	08Jan2018	03Feb2018		AE-3
		06JAN2016	24MAR2016	Ibuprophen 400 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 03)	1-0-1	08Jan2018	03Feb2018		AE-3
		06JAN2016	24MAR2016	Ibuprophen 400 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 03)	1-0-1	08Jan2018	03Feb2018		AE-3
		06JAN2016	24MAR2016	Ibuprophen 400 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 03)	1-0-1	08Jan2018	03Feb2018		AE-3
		06JAN2016	24MAR2016	Ibuprophen 400 mg	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 03)	1-0-1	08Jan2018	03Feb2018		AE-3
		06JAN2016	24MAR2016	Cefazolin 2 g	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic treatment	0-2g-0	06Jan2016	06Jan2016		
		06JAN2016	24MAR2016	Iberogast 20°	IBEROGAST	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	Other: Prophylaxe (AE no. 02)	1x20°	12Dec2016	13Dec2016		AE-2
		06JAN2016	24MAR2016	Ibuprophen 400 mg	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 03)	if nessasary	04Feb2018	26Feb2018		AE-3
		06JAN2016	24MAR2016	Ibuprophen 400 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 03)	if nessasary	04Feb2018	26Feb2018		AE-3

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0915	ND basic	06JAN2016	24MAR2016	Ibuprophen 400 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 03)	if nessasary	04Feb2018	26Feb2018		AE-3
		06JAN2016	24MAR2016	Ibuprophen 400 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 03)	if nessasary	04Feb2018	26Feb2018		AE-3
		06JAN2016	24MAR2016	Ibuprophen 400 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 03)	if nessasary	04Feb2018	26Feb2018		AE-3
		06JAN2016	24MAR2016	Ibuprophen 400 mg	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 02)	3x400 mg	29Dec2016	05Jan2017		AE-2
		06JAN2016	24MAR2016	Ibuprophen 400 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 02)	3x400 mg	29Dec2016	05Jan2017		AE-2
		06JAN2016	24MAR2016	Ibuprophen 400 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 02)	3x400 mg	29Dec2016	05Jan2017		AE-2
		06JAN2016	24MAR2016	Ibuprophen 400 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 02)	3x400 mg	29Dec2016	05Jan2017		AE-2
		06JAN2016	24MAR2016	Ibuprophen 400 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 02)	3x400 mg	29Dec2016	05Jan2017		AE-2
09/0916	SC	23FEB2016	-	Certoparin 3000 iE. sc.	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Antithrombotic	0-0-1	24Feb2016	28Feb2016		
		23FEB2016	-	Monoembolex 800 i.E. s.c.	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Peripheral pulmonary embolism (AE no. 04)	1-0-1	18Nov2016	25Nov2016		AE-4
		23FEB2016	-	Lixiana 60 mg Tbl.	EDOXABAN TOSILATE	ANTITHROMBOTIC AGENTS	Other: peripheral pulmonary embolism (AE no. 04)	0-0-1	25Nov2016	01May2018		AE-4

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0916	SC	23FEB2016	-	ASS 100 mg	ACETYLSALICYLIC ACID	ANTITHROMBOTIC AGENTS	Other: prophylaxis (AE no. 04)	1-0-0	02May2017		Yes	AE-4
		23FEB2016	-	ASS 100 mg	ACETYLSALICYLIC ACID	STOMATOLOGICAL PREPARATIONS	Other: prophylaxis (AE no. 04)	1-0-0	02May2017		Yes	AE-4
		23FEB2016	-	ASS 100 mg	ACETYLSALICYLIC ACID	ANALGESICS	Other: prophylaxis (AE no. 04)	1-0-0	02May2017		Yes	AE-4
		23FEB2016	-	ASS 100 mg	ACETYLSALICYLIC ACID	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: prophylaxis (AE no. 04)	1-0-0	02May2017		Yes	AE-4
		23FEB2016	-	Unacid 3 gr. i.v.	UNACID /00917901/	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Peripheral pulmonary embolism (AE no. 04)	1-1-1	18Nov2016	25Nov2016		AE-4
		23FEB2016	-	Ibuhexal 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 05)	1-0-1	03Oct2017	14Oct2017		AE-5
		23FEB2016	-	Ibuhexal 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 05)	1-0-1	03Oct2017	14Oct2017		AE-5
		23FEB2016	-	Ibuhexal 600 mg	IBUPROFEN	ANTIINFLAMMATO RY AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 05)	1-0-1	03Oct2017	14Oct2017		AE-5
		23FEB2016	-	Ibuhexal 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 05)	1-0-1	03Oct2017	14Oct2017		AE-5
		23FEB2016	-	Ibuhexal 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 05)	1-0-1	03Oct2017	14Oct2017		AE-5
		23FEB2016	-	Certoparin 8000 iE. sc.	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Cardiac arrhythmia (AE no. 01)	0-0-1	29Feb2016	17Mar2016		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0916	SC	23FEB2016	-	Ibuprophen 400 mg Tbl.	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: Peripheral pulmonary embolism (AE no. 04)	1-1-1	18Nov2016	22Nov2016		AE-4
		23FEB2016	-	Ibuprophen 400 mg Tbl.	IBUPROFEN	OTHER GYNECOLOGICALS	Other: Peripheral pulmonary embolism (AE no. 04)	1-1-1	18Nov2016	22Nov2016		AE-4
		23FEB2016	-	Ibuprophen 400 mg Tbl.	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: Peripheral pulmonary embolism (AE no. 04)	1-1-1	18Nov2016	22Nov2016		AE-4
		23FEB2016	-	Ibuprophen 400 mg Tbl.	IBUPROFEN	CARDIAC THERAPY	Other: Peripheral pulmonary embolism (AE no. 04)	1-1-1	18Nov2016	22Nov2016		AE-4
		23FEB2016	-	Ibuprophen 400 mg Tbl.	IBUPROFEN	THROAT PREPARATIONS	Other: Peripheral pulmonary embolism (AE no. 04)	1-1-1	18Nov2016	22Nov2016		AE-4
		23FEB2016	-	Cefazolin 2 g	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Antibiotic	0-2g-0	23Feb2016	23Feb2016		
		23FEB2016	-	Paracetamol 500 mg Tbl.	PARACETAMOL	ANALGESICS	Other: Peripheral pulmonary embolism (AE no. 04)	0-0-1	23Nov2016	25Nov2016		AE-4
11/1101	ND plus	13JAN2015	31MAR2015	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-other	100 mg	18Jan2015	Jan2015		
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: postop anti-inflammato ry	24 mg	16Jan2015	18Jan2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
11/1101	ND plus	13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Other: postop anti-inflammato ry	24 mg	16Jan2015	18Jan2015	
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: postop anti-inflammato ry	24 mg	16Jan2015	18Jan2015	
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Other: postop anti-inflammato ry	24 mg	16Jan2015	18Jan2015	
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	Other: postop anti-inflammato ry	24 mg	16Jan2015	18Jan2015	
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: postop anti-inflammato ry	24 mg	16Jan2015	18Jan2015	
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	Other: postop anti-inflammato ry	24 mg	16Jan2015	18Jan2015	
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: postop anti-inflammato ry	24 mg	16Jan2015	18Jan2015	
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	Other: postop anti-inflammato ry	24 mg	16Jan2015	18Jan2015	
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	OTOLOGICALS	Other: postop anti-inflammato ry	24 mg	16Jan2015	18Jan2015	
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: postop anti-inflammato ry	24 mg	16Jan2015	18Jan2015	
		13JAN2015	31MAR2015	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: stomach protection	40 mg	31Mar2015	02Apr2015	
		13JAN2015	31MAR2015	Unacid	UNACID	ANTIBACTERIALS FOR SYSTEMIC USE	Other: OP prophylaxis	3 g	13Jan2015	13Jan2015	

/00917901/

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1101	ND plus	13JAN2015	31MAR2015	Akrinor 2 ml/10 ml	AKRINOR	CARDIAC THERAPY	Other: OP hypnotic	6 ml	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Metamizol	METAMIZOLE	ANALGESICS	Other: OP analgetic	2 g	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Dipidolor	PIRITRAMIDE	ANALGESICS	Other: OP analgetic	3 mg	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Ibuprofen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 04)	1800 mg	Jan2017	08Oct2017		AE-4
		13JAN2015	31MAR2015	Ibuprofen 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 04)	1800 mg	Jan2017	08Oct2017		AE-4
		13JAN2015	31MAR2015	Ibuprofen 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 04)	1800 mg	Jan2017	08Oct2017		AE-4
		13JAN2015	31MAR2015	Ibuprofen 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 04)	1800 mg	Jan2017	08Oct2017		AE-4
		13JAN2015	31MAR2015	Ibuprofen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 04)	1800 mg	Jan2017	08Oct2017		AE-4
		13JAN2015	31MAR2015	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: stomach protection (AE no. 05)	40 mg	28Sep2017	08Oct2017		AE-5
		13JAN2015	31MAR2015	Parecoxib	PARECOXIB	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: OP Analgetikum (AE no. 05)	40 mg i.v.	27Sep2017	27Sep2017		AE-5
		13JAN2015	31MAR2015	Poli electrolytic solution	ELECTROLYTE SOLUTIONS	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: OP Prophylaxis (AE no. 05)	1000 mL i.v.	27Sep2017	27Sep2017		AE-5
		13JAN2015	31MAR2015	Bupiracaim 0.5 %	/90010101/ (90010101001) BUPIVACAINE	ANESTHETICS	Other: periradicular therapy (AE no. 06)	2 mL	26Mar2018	26Mar2018		AE-6

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1101	ND plus	13JAN2015	31MAR2015	Bupiracaim 0.5 %	BUPIVACAINE	OPHTHALMOLOGICA LS	Other: periradicular therapy (AE no. 06)	2 mL	26Mar2018	26Mar2018		AE-6
		13JAN2015	31MAR2015	Lidocain 1.0 %	LIDOCAINE	ANESTHETICS	Other: periradicular therapy (AE no. 06)	10 ml	15Aug2018	15Aug2018		AE-6
		13JAN2015	31MAR2015	Lidocain 1.0 %	LIDOCAINE	UROLOGICALS	Other: periradicular therapy (AE no. 06)	10 ml	15Aug2018	15Aug2018		AE-6
		13JAN2015	31MAR2015	Lidocain 1.0 %	LIDOCAINE	ANTIPRURITICS, INCL. ANTI HISTAMINES, ANESTHETICS, ETC.	Other: periradicular therapy (AE no. 06)	10 ml	15Aug2018	15Aug2018		AE-6
		13JAN2015	31MAR2015	Lidocain 1.0 %	LIDOCAINE	STOMATOLOGICAL PREPARATIONS	Other: periradicular therapy (AE no. 06)	10 ml	15Aug2018	15Aug2018		AE-6
		13JAN2015	31MAR2015	Lidocain 1.0 %	LIDOCAINE	CARDIAC THERAPY	Other: periradicular therapy (AE no. 06)	10 ml	15Aug2018	15Aug2018		AE-6
		13JAN2015	31MAR2015	Lidocain 1.0 %	LIDOCAINE	VASOPROTECTIVES	Other: periradicular therapy (AE no. 06)	10 ml	15Aug2018	15Aug2018		AE-6
		13JAN2015	31MAR2015	Lidocain 1.0 %	LIDOCAINE	OTOLOGICALS	Other: periradicular therapy (AE no. 06)	10 ml	15Aug2018	15Aug2018		AE-6
		13JAN2015	31MAR2015	Lidocain 1.0 %	LIDOCAINE	THROAT PREPARATIONS	Other: periradicular therapy (AE no. 06)	10 ml	15Aug2018	15Aug2018		AE-6

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1101	ND plus	13JAN2015	31MAR2015	Lidocain 1.0 %	LIDOCAINE	OPHTHALMOLOGICA LS	Other: periradicular therapy (AE no. 06)	10 ml	15Aug2018	15Aug2018		AE-6
		13JAN2015	31MAR2015	Vigantoletten	COLECALCIFEROL	VITAMINS	Other: Vitamin D deficiency (AE no. 08)	2000 iE	Oct2018	Jun2019		AE-8
		13JAN2015	31MAR2015	Piritramid	PIRITRAMIDE	ANALGESICS	Other: OP analgesic (AE no. 10)	25 mg	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Remifentanil 2000 ug	REMIFENTANIL	ANESTHETICS	Other: OP anesthetic (AE no. 10)	40 ug	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Parecoxib	PARECOXIB	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: OP prophylaxis postop pain (AE no. 10)	40 mg	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Fraxiparin	NADROPARIN CALCIUM	ANTITHROMBOTIC AGENTS	Other: post-op thrombosis-prop hylaxis (AE no. 10)	0.4 ml	01Aug2019	03Aug2019		AE-10
		13JAN2015	31MAR2015	Bifiteral	LACTULOSE	DRUGS FOR CONSTIPATION	Other: postop obstipation prophylaxis (AE no. 10)	NA	01Aug2019	03Aug2019		AE-10
		13JAN2015	31MAR2015	Bifiteral	LACTULOSE	BILE AND LIVER THERAPY	Other: postop obstipation prophylaxis (AE no. 10)	NA	01Aug2019	03Aug2019		AE-10
		13JAN2015	31MAR2015	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: stomach protection	40 mg	14Jan2015	19Jan2015		
		13JAN2015	31MAR2015	Vomex	DIMENHYDRINATE	ANTIEMETICS AND ANTINAUSEANTS	Other: emesis	3 Drg	15Jan2015	17Jan2015		
		13JAN2015	31MAR2015	Vomex	DIMENHYDRINATE	OTHER NERVOUS SYSTEM DRUGS	Other: emesis	3 Drg	15Jan2015	17Jan2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1101	ND plus	13JAN2015	31MAR2015	Vomex	DIMENHYDRINATE	ANTIHIISTAMINES FOR SYSTEMIC USE	Other: emesis	3 Drg	15Jan2015	17Jan2015		
		13JAN2015	31MAR2015	Fentanyl	FENTANYL	ANESTHETICS	Other: OP analgetic	0.6 mg	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Fentanyl	FENTANYL	ANALGESICS	Other: OP analgetic	0.6 mg	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Sterofundin	HAEMOFILTRATION SLOESUNG HF 24	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: OP Prophylaxis	1000 ml	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Zofran	ONDANSETRON	ANTIEMETICS AND ANTINAUSEANTS	Other: OP Prophylaxis	4 mg	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Lidocain	LIDOCAINE	ANESTHETICS	Other: Local anaesthesia	2% 1 Amp a 10 ml	31Mar2015	31Mar2015		
		13JAN2015	31MAR2015	Lidocain	LIDOCAINE	ANTIPRURITICS, INCL. ANTIHIISTAMINES, ANESTHETICS, ETC.	Other: Local anaesthesia	2% 1 Amp a 10 ml	31Mar2015	31Mar2015		
		13JAN2015	31MAR2015	Lidocain	LIDOCAINE	UROLOGICALS	Other: Local anaesthesia	2% 1 Amp a 10 ml	31Mar2015	31Mar2015		
		13JAN2015	31MAR2015	Lidocain	LIDOCAINE	STOMATOLOGICAL PREPARATIONS	Other: Local anaesthesia	2% 1 Amp a 10 ml	31Mar2015	31Mar2015		
		13JAN2015	31MAR2015	Lidocain	LIDOCAINE	CARDIAC THERAPY	Other: Local anaesthesia	2% 1 Amp a 10 ml	31Mar2015	31Mar2015		
		13JAN2015	31MAR2015	Lidocain	LIDOCAINE	VASOPROTECTIVES	Other: Local anaesthesia	2% 1 Amp a 10 ml	31Mar2015	31Mar2015		
		13JAN2015	31MAR2015	Lidocain	LIDOCAINE	OTOLOGICALS	Other: Local anaesthesia	2% 1 Amp a 10 ml	31Mar2015	31Mar2015		
		13JAN2015	31MAR2015	Lidocain	LIDOCAINE	OPHTHALMOLOGICA LS	Other: Local anaesthesia	2% 1 Amp a 10 ml	31Mar2015	31Mar2015		
		13JAN2015	31MAR2015	Lidocain	LIDOCAINE	THROAT PREPARATIONS	Other: Local anaesthesia	2% 1 Amp a 10 ml	31Mar2015	31Mar2015		
		13JAN2015	31MAR2015	Movicol	OSMOTICALLY ACTING LAXATIVES (90062401001)	DRUGS FOR CONSTIPATION	Other: postop obstipation prophylaxis (AE no. 05)	1 sachet daily	28Sep2017	29Sep2017		AE-5

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1101	ND plus	13JAN2015	31MAR2015	Cafedrin	CAFEDRINE	CARDIAC THERAPY	Other: OP Hypertonikum (AE no. 05)	40 mg i.v.	27Sep2017	27Sep2017		AE-5
		13JAN2015	31MAR2015	Propofol MCT 1000 mg	PROPOFOL	ANESTHETICS	Other: OP Narkotikum (AE no. 05)	6 mg/kg/h over 1.5. h i.v.	27Sep2017	27Sep2017		AE-5
		13JAN2015	31MAR2015	Frisium	CLOBAZAM	ANTIEPILEPTICS	Other: cryptogenic oligoepilepsia (AE no. 07)	10 mg as needed	Nov2017	Jan2019		AE-7
		13JAN2015	31MAR2015	Frisium	CLOBAZAM	PSYCHOLEPTICS	Other: cryptogenic oligoepilepsia (AE no. 07)	10 mg as needed	Nov2017	Jan2019		AE-7
		13JAN2015	31MAR2015	Triam 40	TRIAMCINOLONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: periradicular therapy (AE no. 06)	1 mL	26Mar2018	26Mar2018		AE-6
		13JAN2015	31MAR2015	Triam 40	TRIAMCINOLONE	OPHTHALMOLOGICA LS	Other: periradicular therapy (AE no. 06)	1 mL	26Mar2018	26Mar2018		AE-6
		13JAN2015	31MAR2015	Triam 40	TRIAMCINOLONE	NASAL PREPARATIONS	Other: periradicular therapy (AE no. 06)	1 mL	26Mar2018	26Mar2018		AE-6
		13JAN2015	31MAR2015	Triam 40	TRIAMCINOLONE	VASOPROTECTIVES	Other: periradicular therapy (AE no. 06)	1 mL	26Mar2018	26Mar2018		AE-6
		13JAN2015	31MAR2015	Triam 40	TRIAMCINOLONE	STOMATOLOGICAL PREPARATIONS	Other: periradicular therapy (AE no. 06)	1 mL	26Mar2018	26Mar2018		AE-6
		13JAN2015	31MAR2015	Triam 40	TRIAMCINOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: periradicular therapy (AE no. 06)	1 mL	26Mar2018	26Mar2018		AE-6

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1101	ND plus	13JAN2015	31MAR2015	Triam 40	TRIAMCINOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: periradicular therapy (AE no. 06)	1 mL	26Mar2018	26Mar2018		AE-6
		13JAN2015	31MAR2015	Accupaque 240	IOHEXOL	CONTRAST MEDIA	Other: periradicular therapy (AE no. 06)	1 ml	15Aug2018	15Aug2018		AE-6
		13JAN2015	31MAR2015	Cafedrin	CAFEDRINE	CARDIAC THERAPY	Other: OP hypertonikum (AE no. 10)	80 mg	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Propofol MCT 1000 mg	PROPOFOL	ANESTHETICS	Other: OP narcotic (AE no. 10)	35 mg/kg/h	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Full electrolyte solution	ELECTROLYTE SOLUTIONS	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: OP prophylaxis (AE no. 10)	1500 ml	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Movicol	/90010101/ (90010101001) OSMOTICALLY ACTING LAXATIVES	DRUGS FOR CONSTIPATION	Other: postop obstipation prophylaxis (AE no. 10)	1 Bag	01Aug2019	03Aug2019		AE-10
		13JAN2015	31MAR2015	Laxans (Natrium picosulfat-1-wate r Natriumbenzoat Sorbitol 70, Sorbitol Natriumcitrat-2-w ater citric acid)	SODIUM PICOSULFATE	DRUGS FOR CONSTIPATION	Other: postop obstipation prophylaxis (AE no. 10)	10°	02Aug2019	03Aug2019		AE-10
		13JAN2015	31MAR2015	Movicol	OSMOTICALLY ACTING LAXATIVES (90062401001)	DRUGS FOR CONSTIPATION	Other: postop obstipation prophylaxe	1 sachet daily	14Jan2015	19Jan2015		
		13JAN2015	31MAR2015	Vomex	DIMENHYDRINATE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: emesis	1 Drg	18Jan2015	Jan2015		
		13JAN2015	31MAR2015	Vomex	DIMENHYDRINATE	OTHER NERVOUS SYSTEM DRUGS	Other: emesis	1 Drg	18Jan2015	Jan2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1101	ND plus	13JAN2015	31MAR2015	Vomex	DIMENHYDRINATE	ANTIEMETICS AND ANTINAUSEANTS	Other: emesis	1 Drg	18Jan2015	Jan2015		
		13JAN2015	31MAR2015	Fraxiparin	NADROPARIN CALCIUM	ANTITHROMBOTIC AGENTS	Other: postop thrombosis prophylaxis	0.4 mL s.c.	13Jan2015	19Jan2015		
		13JAN2015	31MAR2015	Propofol	PROPOFOL	ANESTHETICS	Other: OP narcotic	160/20 mg	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Desfluran	DESFLURANE	ANESTHETICS	Other: OP narcotic		13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Morphin	MORPHINE	ANALGESICS	Other: OP analgetic	10 mg/1 ml	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 01)	600 mg as needed	01Oct2015	Nov2015		AE-1
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 01)	600 mg as needed	01Oct2015	Nov2015		AE-1
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 01)	600 mg as needed	01Oct2015	Nov2015		AE-1
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 01)	600 mg as needed	01Oct2015	Nov2015		AE-1
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 01)	600 mg as needed	01Oct2015	Nov2015		AE-1
		13JAN2015	31MAR2015	Fraxiparin	NADROPARIN CALCIUM	ANTITHROMBOTIC AGENTS	Other: postop Thrombosis prophylaxis (AE no. 05)	0.4 ml s.c.	28Sep2017	29Sep2017		AE-5
		13JAN2015	31MAR2015	Cisatracurium	CISATRACURIUM	MUSCLE RELAXANTS	Other: OP muscle relaxant (AE no. 05)	8 mg i.v.	27Sep2017	27Sep2017		AE-5
		13JAN2015	31MAR2015	Propofol MCT 200 mg	PROPOFOL	ANESTHETICS	Other: OP Narkotikum (AE no. 05)	160 mg i.v.	27Sep2017	27Sep2017		AE-5

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1101	ND plus	13JAN2015	31MAR2015	Lidocain 1.0%	LIDOCAINE	ANESTHETICS	Other: periradicular therapy (AE no. 06)	10 mL	26Mar2018	26Mar2018		AE-6
		13JAN2015	31MAR2015	Lidocain 1.0%	LIDOCAINE	ANTIPRURITICS, INCL. ANTIHIISTAMINES, ANESTHETICS, ETC.	Other: periradicular therapy (AE no. 06)	10 mL	26Mar2018	26Mar2018		AE-6
		13JAN2015	31MAR2015	Lidocain 1.0%	LIDOCAINE	UROLOGICALS	Other: periradicular therapy (AE no. 06)	10 mL	26Mar2018	26Mar2018		AE-6
		13JAN2015	31MAR2015	Lidocain 1.0%	LIDOCAINE	THROAT PREPARATIONS	Other: periradicular therapy (AE no. 06)	10 mL	26Mar2018	26Mar2018		AE-6
		13JAN2015	31MAR2015	Lidocain 1.0%	LIDOCAINE	OPHTHALMOLOGICA LS	Other: periradicular therapy (AE no. 06)	10 mL	26Mar2018	26Mar2018		AE-6
		13JAN2015	31MAR2015	Lidocain 1.0%	LIDOCAINE	CARDIAC THERAPY	Other: periradicular therapy (AE no. 06)	10 mL	26Mar2018	26Mar2018		AE-6
		13JAN2015	31MAR2015	Lidocain 1.0%	LIDOCAINE	VASOPROTECTIVES	Other: periradicular therapy (AE no. 06)	10 mL	26Mar2018	26Mar2018		AE-6
		13JAN2015	31MAR2015	Lidocain 1.0%	LIDOCAINE	STOMATOLOGICAL PREPARATIONS	Other: periradicular therapy (AE no. 06)	10 mL	26Mar2018	26Mar2018		AE-6
		13JAN2015	31MAR2015	Lidocain 1.0%	LIDOCAINE	OTOLOGICALS	Other: periradicular therapy (AE no. 06)	10 mL	26Mar2018	26Mar2018		AE-6

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1101	ND plus	13JAN2015	31MAR2015	Bupivacain 0.5 %	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Other: periradicular therapy (AE no. 06)	2 ml	15Aug2018	15Aug2018		AE-6
		13JAN2015	31MAR2015	Bupivacain 0.5 %	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Other: periradicular therapy (AE no. 06)	2 ml	15Aug2018	15Aug2018		AE-6
		13JAN2015	31MAR2015	Lamotrigin	LAMOTRIGINE	ANTIEPILEPTICS	Other: antiepileptica (AE no. 7)	300 mg	Aug2018	Jun2019		AE-7
		13JAN2015	31MAR2015	Cisatracurium	CISATRACURIUM	MUSCLE RELAXANTS	Other: OP muscle relaxant (AE no. 10)	7 mg	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Propofol MCT 200 mg	PROPOFOL	ANESTHETICS	Other: OP narcotic (AE no. 10)	150 mg	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Cefazolin	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: OP antibiotic (AE no. 10)	4 g	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: postop stomach protection (AE no. 10)	40 mg	01Aug2019	Aug2019		AE-10
		13JAN2015	31MAR2015	Vomex	DIMENHYDRINATE	ANTIEMETICS AND ANTINAUSEANTS	Other: postop prophylaxis nausea (AE no. 10)	2 Dragees	01Aug2019	Aug2019		AE-10
		13JAN2015	31MAR2015	Vomex	DIMENHYDRINATE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: postop prophylaxis nausea (AE no. 10)	2 Dragees	01Aug2019	Aug2019		AE-10
		13JAN2015	31MAR2015	Vomex	DIMENHYDRINATE	OTHER NERVOUS SYSTEM DRUGS	Other: postop prophylaxis nausea (AE no. 10)	2 Dragees	01Aug2019	Aug2019		AE-10
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Other: AE 11 (AE no. 11)	600 mg as needed	11Apr2020			AE-11

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1101	ND plus	13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Other: AE 11 (AE no. 11)	600 mg as needed	11Apr2020			AE-11
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: AE 11 (AE no. 11)	600 mg as needed	11Apr2020			AE-11
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: AE 11 (AE no. 11)	600 mg as needed	11Apr2020			AE-11
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Other: AE 11 (AE no. 11)	600 mg as needed	11Apr2020			AE-11
		13JAN2015	31MAR2015	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-other	300 mg	15Jan2015	17Jan2015		
		13JAN2015	31MAR2015	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Other: muscle relaxant	1500 mg	15Jan2015	19Jan2015		
		13JAN2015	31MAR2015	Rocuronium	ROCURONIUM	MUSCLE RELAXANTS	Other: OP Muscle relaxant	35 mg	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: OP Prophylaxis	4 mg	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Other: OP Prophylaxis	4 mg	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS / DERMATOLOGICAL PREPARATIONS	Other: OP Prophylaxis	4 mg	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	Other: OP Prophylaxis	4 mg	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Other: OP Prophylaxis	4 mg	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: OP Prophylaxis	4 mg	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	OTOLOGICALS	Other: OP Prophylaxis	4 mg	13Jan2015	13Jan2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1101	ND plus	13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: OP Prophylaxis	4 mg	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	Other: OP Prophylaxis	4 mg	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: OP Prophylaxis	4 mg	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	Other: OP Prophylaxis	4 mg	13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	Scandicain	MEPIVACAINE HYDROCHLORIDE	ANESTHETICS	Other: 2. OP local anaesthetic	2% 1 Amp a 10 ml	31Mar2015	31Mar2015		
		13JAN2015	31MAR2015	Diclofenac	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 02)	200 mg	07Mar2016	20Mar2016		AE-2
		13JAN2015	31MAR2015	Diclofenac	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 02)	200 mg	07Mar2016	20Mar2016		AE-2
		13JAN2015	31MAR2015	Diclofenac	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 02)	200 mg	07Mar2016	20Mar2016		AE-2
		13JAN2015	31MAR2015	Diclofenac	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 02)	200 mg	07Mar2016	20Mar2016		AE-2
		13JAN2015	31MAR2015	Diclofenac	DICLOFENAC	THROAT PREPARATIONS	Pain-other (AE no. 02)	200 mg	07Mar2016	20Mar2016		AE-2
		13JAN2015	31MAR2015	Diclofenac	DICLOFENAC	OPHTHALMOLOGICA LS	Pain-other (AE no. 02)	200 mg	07Mar2016	20Mar2016		AE-2
		13JAN2015	31MAR2015	Fentanyl	FENTANYL	ANESTHETICS	Other: OP Analgetikum (AE no. 05)	500 ug i.v.	27Sep2017	27Sep2017		AE-5
		13JAN2015	31MAR2015	Fentanyl	FENTANYL	ANALGESICS	Other: OP Analgetikum (AE no. 05)	500 ug i.v.	27Sep2017	27Sep2017		AE-5
		13JAN2015	31MAR2015	Cefazolin	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: OP Prophylaxis (AE no. 05)	2 g i.v.	27Sep2017	27Sep2017		AE-5

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1101	ND plus	13JAN2015	31MAR2015	Accupaque 240	IOHEXOL	CONTRAST MEDIA	Other: periradicular therapy (AE no. 06)	1 mL	26Mar2018	26Mar2018		AE-6
		13JAN2015	31MAR2015	Triam 40	TRIAMCINOLONE	CORTICOSTEROIDS	Other: periradicular therapy (AE no. 06)	1 ml	15Aug2018	15Aug2018		AE-6
		13JAN2015	31MAR2015	Triam 40	TRIAMCINOLONE	DERMATOLOGICAL PREPARATIONS CORTICOSTEROIDS FOR SYSTEMIC USE	Other: periradicular therapy (AE no. 06)	1 ml	15Aug2018	15Aug2018		AE-6
		13JAN2015	31MAR2015	Triam 40	TRIAMCINOLONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: periradicular therapy (AE no. 06)	1 ml	15Aug2018	15Aug2018		AE-6
		13JAN2015	31MAR2015	Triam 40	TRIAMCINOLONE	OPHTHALMOLOGICA LS	Other: periradicular therapy (AE no. 06)	1 ml	15Aug2018	15Aug2018		AE-6
		13JAN2015	31MAR2015	Triam 40	TRIAMCINOLONE	NASAL PREPARATIONS	Other: periradicular therapy (AE no. 06)	1 ml	15Aug2018	15Aug2018		AE-6
		13JAN2015	31MAR2015	Triam 40	TRIAMCINOLONE	VASOPROTECTIVES	Other: periradicular therapy (AE no. 06)	1 ml	15Aug2018	15Aug2018		AE-6
		13JAN2015	31MAR2015	Triam 40	TRIAMCINOLONE	STOMATOLOGICAL PREPARATIONS	Other: periradicular therapy (AE no. 06)	1 ml	15Aug2018	15Aug2018		AE-6
		13JAN2015	31MAR2015	Lamotrigin	LAMOTRIGINE	ANTIEPILEPTICS	Other: antiepileptica	150 mg	Jun2019		Yes	
		13JAN2015	31MAR2015	Metamizol	METAMIZOLE	ANALGESICS	Other: OP analgesic (AE no. 10)	0.7 g	31Jul2019	31Jul2019		AE-10

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1101	ND plus	13JAN2015	31MAR2015	Remifentanil 2000 ug	REMIFENTANIL	ANESTHETICS	Other: OP anesthetic (AE no. 10)	1.6 ug/kg/min	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Dexamethason	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: OP prophylaxis anti-inflammato ry (AE no. 10)	4 mg	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Dexamethason	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Other: OP prophylaxis anti-inflammato ry (AE no. 10)	4 mg	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Dexamethason	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: OP prophylaxis anti-inflammato ry (AE no. 10)	4 mg	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Dexamethason	DEXAMETHASONE	VASOPROTECTIVES	Other: OP prophylaxis anti-inflammato ry (AE no. 10)	4 mg	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Dexamethason	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Other: OP prophylaxis anti-inflammato ry (AE no. 10)	4 mg	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Dexamethason	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: OP prophylaxis anti-inflammato ry (AE no. 10)	4 mg	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Dexamethason	DEXAMETHASONE	OTOLOGICALS	Other: OP prophylaxis anti-inflammato ry (AE no. 10)	4 mg	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Dexamethason	DEXAMETHASONE	NASAL PREPARATIONS	Other: OP prophylaxis anti-inflammato ry (AE no. 10)	4 mg	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Dexamethason	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: OP prophylaxis anti-inflammato ry (AE no. 10)	4 mg	31Jul2019	31Jul2019		AE-10

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1101	ND plus	13JAN2015	31MAR2015	Dexamethason	DEXAMETHASONE	OPHTHALMOLOGICA LS	Other: OP prophylaxis anti-inflammato ry (AE no. 10)	4 mg	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Dexamethason	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: OP prophylaxis anti-inflammato ry (AE no. 10)	4 mg	31Jul2019	31Jul2019		AE-10
		13JAN2015	31MAR2015	Ionosteril	IONOSTERIL	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: postop substitution liquid (AE no. 10)	500 ml	01Aug2019	01Aug2019		AE-10
		13JAN2015	31MAR2015	Arcoxia	ETORICOXIB	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: AE 11 (AE no. 11)	90 mg as needed	11Apr2020			AE-11
		13JAN2015	31MAR2015	O2	OXYGEN	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: OP narcotic		13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	O2	OXYGEN	ALL OTHER THERAPEUTIC PRODUCTS	Other: OP narcotic		13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	O2	OXYGEN	STOMATOLOGICAL PREPARATIONS	Other: OP narcotic		13Jan2015	13Jan2015		
		13JAN2015	31MAR2015	O2	OXYGEN	OTHER DERMATOLOGICAL PREPARATIONS	Other: OP narcotic		13Jan2015	13Jan2015		
11/1102	ND basic	20APR2015	28JUL2015	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: gastric protection	20 mg	20Apr2015	21Apr2015		
		20APR2015	28JUL2015	Propofol	PROPOFOL	ANESTHETICS	Other: Narcotic	200 mg	20Apr2015	20Apr2015		
		20APR2015	28JUL2015	Clindamycin	CLINDAMYCIN	ANTI-ACNE PREPARATIONS	Other: antibiotic prophylaxis	600 mg	20Apr2015	20Apr2015		
		20APR2015	28JUL2015	Clindamycin	CLINDAMYCIN	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	Other: antibiotic prophylaxis	600 mg	20Apr2015	20Apr2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
11/1102	ND basic	20APR2015	28JUL2015	Clindamycin	CLINDAMYCIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: antibiotic prophylaxis	600 mg	20Apr2015	20Apr2015	
		20APR2015	28JUL2015	Fraxiparin	NADROPARIN CALCIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis	0.4 ml s.c.	20Apr2015	21Apr2015	
		20APR2015	28JUL2015	Rocuronium	ROCURONIUM	MUSCLE RELAXANTS	Other: Muscle relaxant	40 mg	20Apr2015	20Apr2015	
		20APR2015	28JUL2015	Ionoskril	IONOSTERIL	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: Prophylaxe	1000 ml	20Apr2015	20Apr2015	
		20APR2015	28JUL2015	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Other: muscle relaxant	1500 ng	14Apr2015	21Apr2015	
		20APR2015	28JUL2015	Fraxiparin	NADROPARIN CALCIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis	0.4 ml s.c.	14Apr2015	16Apr2015	
		20APR2015	28JUL2015	Akrinor	AKRINOR	CARDIAC THERAPY	Other: hypotonic	2/2 ml	20Apr2015	20Apr2015	
		20APR2015	28JUL2015	Desfluron	DESFLURANE	ANESTHETICS	Other: Narcotic		20Apr2015	20Apr2015	
		20APR2015	28JUL2015	Fentanyl	FENTANYL	ANESTHETICS	Other: anaesthetic, analgetic	0.3 mg	20Apr2015	20Apr2015	
		20APR2015	28JUL2015	Fentanyl	FENTANYL	ANALGESICS	Other: anaesthetic, analgetic	0.3 mg	20Apr2015	20Apr2015	
		20APR2015	28JUL2015	Metamizol	METAMIZOLE	ANALGESICS	Other: Analgesic	2 g	20Apr2015	20Apr2015	
		20APR2015	28JUL2015	O2	OXYGEN	OTHER DERMATOLOGICAL PREPARATIONS	Other: Narcotic		20Apr2015	20Apr2015	
		20APR2015	28JUL2015	O2	OXYGEN	STOMATOLOGICAL PREPARATIONS	Other: Narcotic		20Apr2015	20Apr2015	
		20APR2015	28JUL2015	O2	OXYGEN	ALL OTHER THERAPEUTIC PRODUCTS	Other: Narcotic		20Apr2015	20Apr2015	
		20APR2015	28JUL2015	O2	OXYGEN	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: Narcotic		20Apr2015	20Apr2015	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1103	SC	03AUG2015	-	Sertraline	SERTRALINE	PSYCHOANALEPTIC S	Other: depression (MedHis no. 3)	50 mg	Jul2015		Yes	MH-3
		03AUG2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Other: postop	1800 mg	03Aug2015	10Aug2015		
		03AUG2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Other: postop	1800 mg	03Aug2015	10Aug2015		
		03AUG2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: postop	1800 mg	03Aug2015	10Aug2015		
		03AUG2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Other: postop	1800 mg	03Aug2015	10Aug2015		
		03AUG2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: postop	1800 mg	03Aug2015	10Aug2015		
		03AUG2015	-	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 01)	24 mg/2 days reduced to 6 mg/2 days	04Aug2015	09Aug2015		AE-1
		03AUG2015	-	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Pain-other (AE no. 01)	24 mg/2 days reduced to 6 mg/2 days	04Aug2015	09Aug2015		AE-1
		03AUG2015	-	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 01)	24 mg/2 days reduced to 6 mg/2 days	04Aug2015	09Aug2015		AE-1
		03AUG2015	-	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	Pain-other (AE no. 01)	24 mg/2 days reduced to 6 mg/2 days	04Aug2015	09Aug2015		AE-1
		03AUG2015	-	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-other (AE no. 01)	24 mg/2 days reduced to 6 mg/2 days	04Aug2015	09Aug2015		AE-1
		03AUG2015	-	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	Pain-other (AE no. 01)	24 mg/2 days reduced to 6 mg/2 days	04Aug2015	09Aug2015		AE-1
		03AUG2015	-	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Pain-other (AE no. 01)	24 mg/2 days reduced to 6 mg/2 days	04Aug2015	09Aug2015		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1103	SC	03AUG2015	-	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 01)	24 mg/2 days reduced to 6 mg/2 days	04Aug2015	09Aug2015		AE-1
		03AUG2015	-	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	Pain-other (AE no. 01)	24 mg/2 days reduced to 6 mg/2 days	04Aug2015	09Aug2015		AE-1
		03AUG2015	-	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Pain-other (AE no. 01)	24 mg/2 days reduced to 6 mg/2 days	04Aug2015	09Aug2015		AE-1
		03AUG2015	-	Fortecortin	DEXAMETHASONE	OTOLOGICALS	Pain-other (AE no. 01)	24 mg/2 days reduced to 6 mg/2 days	04Aug2015	09Aug2015		AE-1
		03AUG2015	-	Propofol	PROPOFOL	ANESTHETICS	Other: OP narcotic	300 mg	03Aug2015	03Aug2015		
		03AUG2015	-	Novalgine (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Other: OP analgetic	2 g	03Aug2015	03Aug2015		
		03AUG2015	-	Vit. D	VITAMIN D NOS	VITAMINS	Other: gyn Prophylaxis	20000 iE once per week	Feb2017	2018		
		03AUG2015	-	Norepinephrin	NOREPINEPHRINE	CARDIAC THERAPY	Other: OP Hypotonikum (AE no. 07)	0.06 ug	05Jan2018	05Jan2018		AE-7
		03AUG2015	-	Propofol MCT 1000 mg	PROPOFOL	ANESTHETICS	Other: OP narcotic (AE no. 07)	8 mg	05Jan2018	05Jan2018		AE-7
		03AUG2015	-	full electrolyte solution	ELECTROLYTE SOLUTIONS /90010101/ (90010101001)	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: OP prophylaxis (AE no. 07)	1500 ml	05Jan2018	05Jan2018		AE-7
		03AUG2015	-	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Other: anti-inflammato ry (AE no. 07)	24 mg	12Jan2018	14Jan2018		AE-7
		03AUG2015	-	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: anti-inflammato ry (AE no. 07)	24 mg	12Jan2018	14Jan2018		AE-7

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1103	SC	03AUG2015	-	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: anti-inflammato ry (AE no. 07)	24 mg	12Jan2018	14Jan2018		AE-7
		03AUG2015	-	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: anti-inflammato ry (AE no. 07)	24 mg	12Jan2018	14Jan2018		AE-7
		03AUG2015	-	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	Other: anti-inflammato ry (AE no. 07)	24 mg	12Jan2018	14Jan2018		AE-7
		03AUG2015	-	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: anti-inflammato ry (AE no. 07)	24 mg	12Jan2018	14Jan2018		AE-7
		03AUG2015	-	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	Other: anti-inflammato ry (AE no. 07)	24 mg	12Jan2018	14Jan2018		AE-7
		03AUG2015	-	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: anti-inflammato ry (AE no. 07)	24 mg	12Jan2018	14Jan2018		AE-7
		03AUG2015	-	Fortecortin	DEXAMETHASONE	OTOLOGICALS	Other: anti-inflammato ry (AE no. 07)	24 mg	12Jan2018	14Jan2018		AE-7
		03AUG2015	-	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	Other: anti-inflammato ry (AE no. 07)	24 mg	12Jan2018	14Jan2018		AE-7
		03AUG2015	-	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Other: anti-inflammato ry (AE no. 07)	24 mg	12Jan2018	14Jan2018		AE-7
		03AUG2015	-	Cisatracurium	CISATRACURIUM	MUSCLE RELAXANTS	Other: muscle relaxant (AE no. 07)	8 mg	10Jan2018	10Jan2018		AE-7
		03AUG2015	-	Propofol MCT 1000 mg	PROPOFOL	ANESTHETICS	Other: narcotic (AE no. 07)	25 mg	10Jan2018	10Jan2018		AE-7
		03AUG2015	-	full electrolyte solution	ELECTROLYTE SOLUTIONS /90010101/ (90010101001)	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: prophylaxis (AE no. 07)	1000 ml	10Jan2018	10Jan2018		AE-7

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1103	SC	03AUG2015	-	Metoclopramid	METOCLOPRAMIDE	DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	Other: antiemetic (AE no. 09)	10 mg	13Feb2018	14Feb2018		AE-9
		03AUG2015	-	Sertraline	SERTRALINE	PSYCHOANALEPTIC S	Other: depression	100 mg	Dec2014		Yes	
		03AUG2015	-	Carbostesin 0.5 %	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICAL LS	Other: facet syndrome (AE no. 09)	5 ml	20Feb2018	20Feb2018		AE-9
		03AUG2015	-	Carbostesin 0.5 %	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Other: facet syndrome (AE no. 09)	5 ml	20Feb2018	20Feb2018		AE-9
		03AUG2015	-	Lipotalon	DEXAMETHASONE PALMITATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: facet syndrome (AE no. 09)	2 ml	28Feb2018	28Feb2018		AE-9
		03AUG2015	-	Lipotalon	DEXAMETHASONE PALMITATE	ANTI-ACNE PREPARATIONS	Other: facet syndrome (AE no. 09)	2 ml	28Feb2018	28Feb2018		AE-9
		03AUG2015	-	Lipotalon	DEXAMETHASONE PALMITATE	VASOPROTECTIVES	Other: facet syndrome (AE no. 09)	2 ml	28Feb2018	28Feb2018		AE-9
		03AUG2015	-	Lipotalon	DEXAMETHASONE PALMITATE	STOMATOLOGICAL PREPARATIONS	Other: facet syndrome (AE no. 09)	2 ml	28Feb2018	28Feb2018		AE-9
		03AUG2015	-	Lipotalon	DEXAMETHASONE PALMITATE	OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	Other: facet syndrome (AE no. 09)	2 ml	28Feb2018	28Feb2018		AE-9
		03AUG2015	-	Lipotalon	DEXAMETHASONE PALMITATE	OTOLOGICALS	Other: facet syndrome (AE no. 09)	2 ml	28Feb2018	28Feb2018		AE-9
		03AUG2015	-	Lipotalon	DEXAMETHASONE PALMITATE	NASAL PREPARATIONS	Other: facet syndrome (AE no. 09)	2 ml	28Feb2018	28Feb2018		AE-9
		03AUG2015	-	Lipotalon	DEXAMETHASONE PALMITATE	OPHTHALMOLOGICAL LS	Other: facet syndrome (AE no. 09)	2 ml	28Feb2018	28Feb2018		AE-9

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1103	SC	03AUG2015	-	Movicol	OSMOTICALLY ACTING LAXATIVES (90062401001)	DRUGS FOR CONSTIPATION	Other: laxative (AE no. 11)	1 bag per day	25Jun2018	28Jun2018		AE-11
		03AUG2015	-	Modafinil	MODAFINIL	PSYCHOANALEPTIC S	Other: Idiopatocal Hypersomnie (AE no. 12)	200 mg	May2019	May2019		AE-12
		03AUG2015	-	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Other: Muscle relaxant	300 mg	May2015	04Aug2015		
		03AUG2015	-	Sevredol	MORPHINE SULFATE	ANALGESICS	Other: postop (AE no. 01)	as needed 10 mg	04Aug2015	14Aug2015		AE-1
		03AUG2015	-	Novalgin in 42 ml NaCl 0.9% ((Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-other (AE no. 01)	4 g iv	03Aug2015	04Aug2015		AE-1
		03AUG2015	-	Rucoronium	ROCURONIUM	MUSCLE RELAXANTS	Other: OP muscle relaxant	40 mg	03Aug2015	03Aug2015		
		03AUG2015	-	Sterofundin	HAEMOFILTRATION SLOESUNG HF 24	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: OP Prophylaxis	1000 ml	03Aug2015	03Aug2015		
		03AUG2015	-	Cisatracurium	CISATRACURIUM	MUSCLE RELAXANTS	Other: OP muscle relaxant (AE no. 07)	8 mg	05Jan2018	05Jan2018		AE-7
		03AUG2015	-	Propofol MCT 200 mg	PROPOFOL	ANESTHETICS	Other: OP narcotic (AE no. 07)	200 mg	05Jan2018	05Jan2018		AE-7
		03AUG2015	-	Fraxiparin	NADROPARIN CALCIUM	ANTITHROMBOTIC AGENTS	Other: prophylaxis thrombosis (AE no. 07)	0.4 ml s.c.	05Jan2018	15Jan2018		AE-7
		03AUG2015	-	Atropin	ATROPINE	DRUGS FOR FUNCTIONAL GASTROINTESTINA L DISORDERS	Other: muscle relaxant (AE no. 07)	0.50 mg	10Jan2018	10Jan2018		AE-7
		03AUG2015	-	Atropin	ATROPINE	CARDIAC THERAPY	Other: muscle relaxant (AE no. 07)	0.50 mg	10Jan2018	10Jan2018		AE-7

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1103	SC	03AUG2015	-	Atropin	ATROPINE	ALL OTHER THERAPEUTIC PRODUCTS	Other: muscle relaxant (AE no. 07)	0.50 mg	10Jan2018	10Jan2018		AE-7
		03AUG2015	-	Atropin	ATROPINE	OPHTHALMOLOGICA LS	Other: muscle relaxant (AE no. 07)	0.50 mg	10Jan2018	10Jan2018		AE-7
		03AUG2015	-	Fentanyl	FENTANYL	ANESTHETICS	Other: analgesic (AE no. 07)	500 ug	10Jan2018	10Jan2018		AE-7
		03AUG2015	-	Propofol MCT 200 mg	PROPOFOL	ANESTHETICS	Other: narcotic (AE no. 07)	450 mg	10Jan2018	10Jan2018		AE-7
		03AUG2015	-	Ondansetron	ONDANSETRON	ANTIEMETICS AND ANTINAUSEANTS	Other: antiemetic (AE no. 07)	4 mg	10Jan2018	10Jan2018		AE-7
		03AUG2015	-	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Other: anti-inflammato ry (AE no. 09)	24 mg	14Feb2018	16Feb2018		AE-9
		03AUG2015	-	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	Other: anti-inflammato ry (AE no. 09)	24 mg	14Feb2018	16Feb2018		AE-9
		03AUG2015	-	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: anti-inflammato ry (AE no. 09)	24 mg	14Feb2018	16Feb2018		AE-9
		03AUG2015	-	Fortecortin	DEXAMETHASONE	OTOLOGICALS	Other: anti-inflammato ry (AE no. 09)	24 mg	14Feb2018	16Feb2018		AE-9
		03AUG2015	-	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	Other: anti-inflammato ry (AE no. 09)	24 mg	14Feb2018	16Feb2018		AE-9
		03AUG2015	-	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: anti-inflammato ry (AE no. 09)	24 mg	14Feb2018	16Feb2018		AE-9
		03AUG2015	-	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	Other: anti-inflammato ry (AE no. 09)	24 mg	14Feb2018	16Feb2018		AE-9

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1103	SC	03AUG2015	-	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: anti-inflammato ry (AE no. 09)	24 mg	14Feb2018	16Feb2018		AE-9
		03AUG2015	-	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: anti-inflammato ry (AE no. 09)	24 mg	14Feb2018	16Feb2018		AE-9
		03AUG2015	-	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Other: anti-inflammato ry (AE no. 09)	24 mg	14Feb2018	16Feb2018		AE-9
		03AUG2015	-	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS /DERMATOLOGICAL PREPARATIONS	Other: anti-inflammato ry (AE no. 09)	24 mg	14Feb2018	16Feb2018		AE-9
		03AUG2015	-	Fraxiparin	NADROPARIN CALCIUM	ANTITHROMBOTIC AGENTS	Other: prophylaxis thrombosis (AE no. 09)	0.3 ml subcutan	14Feb2018	28Feb2018		AE-9
		03AUG2015	-	Scandicain 2 %	MEPIVACAINE HYDROCHLORIDE	ANESTHETICS	Other: facet syndrome (AE no. 09)	5 ml	20Feb2018	20Feb2018		AE-9
		03AUG2015	-	Carbostesin	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Other: facet syndrome (AE no. 09)	4 ml	28Feb2018	28Feb2018		AE-9
		03AUG2015	-	Carbostesin	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Other: facet syndrome (AE no. 09)	4 ml	28Feb2018	28Feb2018		AE-9
		03AUG2015	-	Movicol (Macroyol 3350)	MOVICOL /01749801/	DRUGS FOR CONSTIPATION	Other: laxative postop	daily 1 bag	04Aug2015	18Aug2015		
		03AUG2015	-	Fraxiparin	NADROPARIN CALCIUM	ANTITHROMBOTIC AGENTS	Other: post Prophylaxe thrombosis	0.3 ml sc 1 x daily	04Aug2015	14Aug2015		
		03AUG2015	-	Cefalexin	CEFALEXIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: OP antibiosis	2 g	03Aug2015	03Aug2015		
		03AUG2015	-	Novalgine NaCl i.v. 42 mL (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-other (AE no. 01)	4 g	07Aug2015	08Aug2015		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1103	SC	03AUG2015	-	Ramipril	RAMIPRIL	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Other: hypertension (AE no. 02)	5 mg	22Sep2015		Yes	AE-2
		03AUG2015	-	Metamizol	METAMIZOLE	ANALGESICS	Other: OP analgesic (AE no. 07)	1 g	05Jan2018	05Jan2018		AE-7
		03AUG2015	-	Remifentanil	REMIFENTANIL	ANESTHETICS	Other: OP analgetic (AE no. 07)	0.55 ug	05Jan2018	05Jan2018		AE-7
		03AUG2015	-	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: stomach protection	40 mg	06Jan2018		Yes	
		03AUG2015	-	Clonidin	CLONIDINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Other: hypotonikum (AE no. 07)	150 ug	10Jan2018	10Jan2018		AE-7
		03AUG2015	-	Clonidin	CLONIDINE HYDROCHLORIDE	PSYCHOANALEPTIC S	Other: hypotonikum (AE no. 07)	150 ug	10Jan2018	10Jan2018		AE-7
		03AUG2015	-	Clonidin	CLONIDINE HYDROCHLORIDE	ANTIHYPERTENSIV ES	Other: hypotonikum (AE no. 07)	150 ug	10Jan2018	10Jan2018		AE-7
		03AUG2015	-	Clonidin	CLONIDINE HYDROCHLORIDE	ANALGESICS	Other: hypotonikum (AE no. 07)	150 ug	10Jan2018	10Jan2018		AE-7
		03AUG2015	-	Remifentanil	REMIFENTANIL	ANESTHETICS	Other: analgetic (AE no. 07)	0.45 ug	10Jan2018	10Jan2018		AE-7
		03AUG2015	-	Movicol	OSMOTICALLY ACTING LAXATIVES (90062401001)	DRUGS FOR CONSTIPATION	Other: laxative (AE no. 09)	1 bag per day	14Feb2018	01Mar2018		AE-9
		03AUG2015	-	Triam (Triamcinolonacit onid)	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: facet syndrome (AE no. 09)	40 mg -> 1 ml	20Feb2018	20Feb2018		AE-9
		03AUG2015	-	Triam (Triamcinolonacit onid)	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: facet syndrome (AE no. 09)	40 mg -> 1 ml	20Feb2018	20Feb2018		AE-9

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1103	SC	03AUG2015	-	Triam (Triamcinolonacit onid)	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: facet syndrome (AE no. 09)	40 mg -> 1 ml	20Feb2018	20Feb2018		AE-9
		03AUG2015	-	Triam (Triamcinolonacit onid)	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICA LS	Other: facet syndrome (AE no. 09)	40 mg -> 1 ml	20Feb2018	20Feb2018		AE-9
		03AUG2015	-	Triam (Triamcinolonacit onid)	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Other: facet syndrome (AE no. 09)	40 mg -> 1 ml	20Feb2018	20Feb2018		AE-9
		03AUG2015	-	Triam (Triamcinolonacit onid)	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Other: facet syndrome (AE no. 09)	40 mg -> 1 ml	20Feb2018	20Feb2018		AE-9
		03AUG2015	-	Triam (Triamcinolonacit onid)	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Other: facet syndrome (AE no. 09)	40 mg -> 1 ml	20Feb2018	20Feb2018		AE-9
		03AUG2015	-	Euthyrox	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hashimoto Thyreoiditis (AE no. 15)	50 mg	Oct2018	Oct2018		AE-15
		03AUG2015	-	Omeprazol	OMEPRAZOLE	DRUGS FOR ACID RELATED DISORDERS	Other: stomach protection	20 mg	May2015	23Nov2015		
		03AUG2015	-	Targin 10 mg	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Other: postop (AE no. 01)	20 mg	04Aug2015	10Aug2015		AE-1
		03AUG2015	-	Targin 10 mg	TARGIN	ANALGESICS	Other: postop (AE no. 01)	20 mg	04Aug2015	10Aug2015		AE-1
		03AUG2015	-	Fentanyl	FENTANYL	ANESTHETICS	Other: OP Analgesic	0.35 mg	03Aug2015	03Aug2015		
		03AUG2015	-	Fentanyl	FENTANYL	ANALGESICS	Other: OP Analgesic	0.35 mg	03Aug2015	03Aug2015		
		03AUG2015	-	Akrinor (1/10)	AKRINOR	CARDIAC THERAPY	Other: OP hypotensive	6 ml	03Aug2015	03Aug2015		
		03AUG2015	-	Lyrica	PREGABALIN	ANALGESICS	Other: Antikonvulsiva (AE no. 01)	50 mg	12Aug2015	12Aug2015		AE-1
		03AUG2015	-	Lyrica	PREGABALIN	ANTIEPILEPTICS	Other: Antikonvulsiva (AE no. 01)	50 mg	12Aug2015	12Aug2015		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1103	SC	03AUG2015	-	Lyrica	PREGABALIN	PSYCHOLEPTICS	Other: Antikonvulsiva (AE no. 01)	50 mg	12Aug2015	12Aug2015		AE-1
		03AUG2015	-	Piritramid	PIRITRAMIDE	ANALGESICS	Other: OP analgesic (AE no. 07)	10 mg	05Jan2018	05Jan2018		AE-7
		03AUG2015	-	Cefazolin	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: OP prophylaxis antibiose (AE no. 07)	4 g	05Jan2018	05Jan2018		AE-7
		03AUG2015	-	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Other: anti-inflammato ry	24 mg	08Jan2018	10Jan2018		
		03AUG2015	-	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	Other: anti-inflammato ry	24 mg	08Jan2018	10Jan2018		
		03AUG2015	-	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: anti-inflammato ry	24 mg	08Jan2018	10Jan2018		
		03AUG2015	-	Fortecortin	DEXAMETHASONE	OTOLOGICALS	Other: anti-inflammato ry	24 mg	08Jan2018	10Jan2018		
		03AUG2015	-	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	Other: anti-inflammato ry	24 mg	08Jan2018	10Jan2018		
		03AUG2015	-	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: anti-inflammato ry	24 mg	08Jan2018	10Jan2018		
		03AUG2015	-	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	Other: anti-inflammato ry	24 mg	08Jan2018	10Jan2018		
		03AUG2015	-	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: anti-inflammato ry	24 mg	08Jan2018	10Jan2018		
		03AUG2015	-	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: anti-inflammato ry	24 mg	08Jan2018	10Jan2018		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1103	SC	03AUG2015	-	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Other: anti-inflammato ry	24 mg	08Jan2018	10Jan2018		
		03AUG2015	-	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: anti-inflammato ry	24 mg	08Jan2018	10Jan2018		
		03AUG2015	-	Movicol	OSMOTICALLY ACTING LAXATIVES (90062401001)	DRUGS FOR CONSTIPATION	Other: laxative (AE no. 07)	1 bag per day	11Jan2018	16Jan2018		AE-7
		03AUG2015	-	Urapidil	URAPIDIL	ANTIHYPERTENSIV ES	Other: hypoton ileum (AE no. 07)	25 mg	10Jan2018	10Jan2018		AE-7
		03AUG2015	-	Cetazolin	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: prophylaxis antibiose (AE no. 07)	2 g	10Jan2018	10Jan2018		AE-7
		03AUG2015	-	Vomex	DIMENHYDRINATE	ANTIEMETICS AND ANTINAUSEANTS	Other: antiemetic (AE no. 09)	1 Drg as needed	14Feb2018	25Feb2018		AE-9
		03AUG2015	-	Vomex	DIMENHYDRINATE	OTHER NERVOUS SYSTEM DRUGS	Other: antiemetic (AE no. 09)	1 Drg as needed	14Feb2018	25Feb2018		AE-9
		03AUG2015	-	Vomex	DIMENHYDRINATE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: antiemetic (AE no. 09)	1 Drg as needed	14Feb2018	25Feb2018		AE-9
		03AUG2015	-	Xylonest 1 %	PRILOCAINE HYDROCHLORIDE	ANESTHETICS	Other: facet syndrome (AE no. 09)	10 ml	28Feb2018	28Feb2018		AE-9
		03AUG2015	-	Modafinil	MODAFINIL	PSYCHOANALEPTIC S	Other: ideopathical hypersomnie (AE no. 12)	100 mg	Aug2018	Sep2018		AE-12
11/1104	ND plus	07MAR2016	08JUN2016	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Other: anti-inflammato ry	12 mg	08Mar2016	10Mar2016		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1104	ND plus	07MAR2016	08JUN2016	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	Other: anti-inflammato ry	12 mg	08Mar2016	10Mar2016		
		07MAR2016	08JUN2016	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: anti-inflammato ry	12 mg	08Mar2016	10Mar2016		
		07MAR2016	08JUN2016	Fortecortin	DEXAMETHASONE	OTOLOGICALS	Other: anti-inflammato ry	12 mg	08Mar2016	10Mar2016		
		07MAR2016	08JUN2016	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: anti-inflammato ry	12 mg	08Mar2016	10Mar2016		
		07MAR2016	08JUN2016	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	Other: anti-inflammato ry	12 mg	08Mar2016	10Mar2016		
		07MAR2016	08JUN2016	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: anti-inflammato ry	12 mg	08Mar2016	10Mar2016		
		07MAR2016	08JUN2016	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	Other: anti-inflammato ry	12 mg	08Mar2016	10Mar2016		
		07MAR2016	08JUN2016	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: anti-inflammato ry	12 mg	08Mar2016	10Mar2016		
		07MAR2016	08JUN2016	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Other: anti-inflammato ry	12 mg	08Mar2016	10Mar2016		
		07MAR2016	08JUN2016	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: anti-inflammato ry	12 mg	08Mar2016	10Mar2016		
		07MAR2016	08JUN2016	Cafedrin	CAFEDRINE	CARDIAC THERAPY	Other: OP stabilization of circulation	40 mg	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Propofol	PROPOFOL	ANESTHETICS	Other: OP narcotic	200 mg	07Mar2016	07Mar2016		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1104	ND plus	07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	VASOPROTECTIVES	Other: OP anti-inflammato ry	4 mg	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Other: OP anti-inflammato ry	4 mg	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: OP anti-inflammato ry	4 mg	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	OTOLOGICALS	Other: OP anti-inflammato ry	4 mg	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	NASAL PREPARATIONS	Other: OP anti-inflammato ry	4 mg	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: OP anti-inflammato ry	4 mg	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	OPHTHALMOLOGICA LS	Other: OP anti-inflammato ry	4 mg	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: OP anti-inflammato ry	4 mg	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: OP anti-inflammato ry	4 mg	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Other: OP anti-inflammato ry	4 mg	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: OP anti-inflammato ry	4 mg	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Movicol	OSMOTICALLY ACTING LAXATIVES (90062401001)	DRUGS FOR CONSTIPATION	Other: postop obstipation (AE no. 01)	2 sachet	09Mar2016	12Mar2016		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1104	ND plus	07MAR2016	08JUN2016	Movicol	OSMOTICALLY ACTING LAXATIVES (90062401001)	DRUGS FOR CONSTIPATION	Other: OP Prophylaxis obstipation	1 sachet	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Metamizol	METAMIZOLE	ANALGESICS	Other: OP pain medication	2 g	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	VASOPROTECTIVES	Other: OP anti-inflammato ry	4 mg	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Other: OP anti-inflammato ry	4 mg	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: OP anti-inflammato ry	4 mg	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	NASAL PREPARATIONS	Other: OP anti-inflammato ry	4 mg	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: OP anti-inflammato ry	4 mg	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	OPHTHALMOLOGICA LS	Other: OP anti-inflammato ry	4 mg	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	OTOLOGICALS	Other: OP anti-inflammato ry	4 mg	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: OP anti-inflammato ry	4 mg	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Other: OP anti-inflammato ry	4 mg	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Other: OP anti-inflammato ry	4 mg	08Jun2016	08Jun2016		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1104	ND plus	07MAR2016	08JUN2016	Dexamethason	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: OP anti-inflammato ry	4 mg	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-other (AE no. 03)	400 mg as needed	Nov2019	Dec2019		AE-3
		07MAR2016	08JUN2016	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 03)	400 mg as needed	Nov2019	Dec2019		AE-3
		07MAR2016	08JUN2016	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-other (AE no. 03)	400 mg as needed	Nov2019	Dec2019		AE-3
		07MAR2016	08JUN2016	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-other (AE no. 03)	400 mg as needed	Nov2019	Dec2019		AE-3
		07MAR2016	08JUN2016	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-other (AE no. 03)	400 mg as needed	Nov2019	Dec2019		AE-3
		07MAR2016	08JUN2016	Fraxiparin	NADROPARIN CALCIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis-proh ylaxis	0.3 mL s.c.	08Mar2016	11Mar2016		
		07MAR2016	08JUN2016	Fentanyl	FENTANYL	ANALGESICS	Other: OP anaesthetic pain medication	450 ug	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Fentanyl	FENTANYL	ANESTHETICS	Other: OP anaesthetic pain medication	450 ug	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Rocuronium	ROCURONIUM	MUSCLE RELAXANTS	Other: OP muscle relaxant	40 mg	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Desfluron	DESFLURANE	ANESTHETICS	Other: OP anaesthetic	4.54 Vol %	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Nitrofurantoin	NITROFURANTOIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: bladder-inflamm ation (AE no. 02)	200 mg	08Apr2016	14Apr2016		AE-2
		07MAR2016	08JUN2016	Ringer solution	COMPOUND SODIUM CHLORIDE /06440701/	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: Substitution	1000 ml	08Jun2016	08Jun2016		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1104	ND plus	07MAR2016	08JUN2016	Ringer solution	COMPOUND SODIUM CHLORIDE /06440701/	NASAL PREPARATIONS	Other: Substitution	1000 ml	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Ringer solution	COMPOUND SODIUM CHLORIDE /06440701/	OTHER DERMATOLOGICAL PREPARATIONS	Other: Substitution	1000 ml	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Propofol	PROPOFOL	ANESTHETICS	Other: OP narcotic	400 mg	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Ondansetron	ONDANSETRON	ANTIEMETICS AND ANTINAUSEANTS	Other: OP antiemetic	4 mg	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Cetirizin	CETIRIZINE HYDROCHLORIDE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: hay fever	5 mg as needed	UNK		Yes	
		07MAR2016	08JUN2016	Cetirizin	CETIRIZINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Other: hay fever	5 mg as needed	UNK		Yes	
		07MAR2016	08JUN2016	Ringer solution	COMPOUND SODIUM CHLORIDE /06440701/	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: OP substituion	500 mL	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Ringer solution	COMPOUND SODIUM CHLORIDE /06440701/	NASAL PREPARATIONS	Other: OP substituion	500 mL	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Ringer solution	COMPOUND SODIUM CHLORIDE /06440701/	OTHER DERMATOLOGICAL PREPARATIONS	Other: OP substituion	500 mL	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Metamizol	METAMIZOLE	ANALGESICS	Other: OP pain medication	2 g	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Cefazolin	CEFAZOLIN	ANTIBACTERIALS FOR SYSTEMIC USE	Other: OP antibiosis	2 g	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Isofluran	ISOFLURANE	ANESTHETICS	Other: OP anaesthetic	0.5 Vol. %	07Mar2016	07Mar2016		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1104	ND plus	07MAR2016	08JUN2016	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: OP pain protection	1800 mg	08Jun2016	09Jun2016		
		07MAR2016	08JUN2016	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Other: OP pain protection	1800 mg	08Jun2016	09Jun2016		
		07MAR2016	08JUN2016	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: OP pain protection	1800 mg	08Jun2016	09Jun2016		
		07MAR2016	08JUN2016	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Other: OP pain protection	1800 mg	08Jun2016	09Jun2016		
		07MAR2016	08JUN2016	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Other: OP pain protection	1800 mg	08Jun2016	09Jun2016		
		07MAR2016	08JUN2016	Cafedrin	CAFEDRINE	CARDIAC THERAPY	Other: OP circuit stabilisation	40 mg	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Rocuronium	ROCURONIUM	MUSCLE RELAXANTS	Other: OP Muscle relaxant	40 mg	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Serofluran	SEVOFLURANE	ANESTHETICS	Other: OP anaesthetic	4.4 Vol %	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: stomach protection	40 mg	06Mar2016	11Mar2016		
		07MAR2016	08JUN2016	Bone wax	SOFT PARAFFIN AND FAT PRODUCTS (90017501001)	EMOLLIENTS AND PROTECTIVES	Other: blood-nursing	1 Package	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Piritramid	PIRITRAMIDE	ANALGESICS	Other: OP analgetic	3 mg	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Full electrolyte solution	ELECTROLYTE SOLUTIONS /90010101/ (90010101001)	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: OP Substitution	1000 ml	07Mar2016	07Mar2016		
		07MAR2016	08JUN2016	Klistier	TRAVAD PHOSPHATE	DRUGS FOR CONSTIPATION	Other: postop obstipation (AE no. 01)	1 pack	09Mar2016	09Mar2016		AE-1

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1104	ND plus	07MAR2016	08JUN2016	Klistier	TRAVAD PHOSPHATE	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: postop obstipation (AE no. 01)	1 pack	09Mar2016	09Mar2016		AE-1
		07MAR2016	08JUN2016	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: stomach protection	40 mg	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Fentanyl	FENTANYL	ANESTHETICS	Other: OP anaesthetic pain medication	300 ug	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Fentanyl	FENTANYL	ANALGESICS	Other: OP anaesthetic pain medication	300 ug	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Full electrolyte solution	ELECTROLYTE SOLUTIONS /90010101/ (90010101001)	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	Other: OP substitution	500 ml	08Jun2016	08Jun2016		
		07MAR2016	08JUN2016	Isofluran	ISOFLURANE	ANESTHETICS	Other: OP anaesthetic	1.3 Vol %	08Jun2016	08Jun2016		
12/1201	ND plus	07SEP2015	01DEC2015	Sotahexal	SOTALOL HYDROCHLORIDE	BETA BLOCKING AGENTS	Other: coronary heart desease (MedHis no. 01)	120 mg	Aug2014			MH-1
		07SEP2015	01DEC2015	Ranitic	RANITIDINE HYDROCHLORIDE	DRUGS FOR ACID RELATED DISORDERS	Other: concomittant to periradicular infiltration	50 mg	28Aug2015	28Aug2015		
		07SEP2015	01DEC2015	Dexamethason	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Other: concomittant to surgical intervention	8 mg	07Sep2015	07Sep2015		
		07SEP2015	01DEC2015	Dexamethason	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Other: concomittant to surgical intervention	8 mg	07Sep2015	07Sep2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
12/1201	ND plus	07SEP2015	01DEC2015	Dexamethason	DEXAMETHASONE	CORTICOSTEROIDS	Other: concomittant to surgical intervention	8 mg	07Sep2015	07Sep2015	
		07SEP2015	01DEC2015	Dexamethason	DEXAMETHASONE	DERMATOLOGICAL PREPARATIONS VASOPROTECTIVES	Other: concomittant to surgical intervention	8 mg	07Sep2015	07Sep2015	
		07SEP2015	01DEC2015	Dexamethason	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Other: concomittant to surgical intervention	8 mg	07Sep2015	07Sep2015	
		07SEP2015	01DEC2015	Dexamethason	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Other: concomittant to surgical intervention	8 mg	07Sep2015	07Sep2015	
		07SEP2015	01DEC2015	Dexamethason	DEXAMETHASONE	OTOLOGICALS	Other: concomittant to surgical intervention	8 mg	07Sep2015	07Sep2015	
		07SEP2015	01DEC2015	Dexamethason	DEXAMETHASONE	OPHTHALMOLOGICA LS	Other: concomittant to surgical intervention	8 mg	07Sep2015	07Sep2015	
		07SEP2015	01DEC2015	Dexamethason	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Other: concomittant to surgical intervention	8 mg	07Sep2015	07Sep2015	
		07SEP2015	01DEC2015	Dexamethason	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Other: concomittant to surgical intervention	8 mg	07Sep2015	07Sep2015	
		07SEP2015	01DEC2015	Dexamethason	DEXAMETHASONE	NASAL PREPARATIONS	Other: concomittant to surgical intervention	8 mg	07Sep2015	07Sep2015	
		07SEP2015	01DEC2015	Cotrim forte	BACTRIM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Prophylaxis	2880 mg	02Dec2015	02Dec2015	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
12/1201	ND plus	07SEP2015	01DEC2015	Mirtazapin	MIRTAZAPINE	PSYCHOANALEPTIC S	Other: Depression (AE no. 06)	15 mg	20May2016	UNK		AE-6
		07SEP2015	01DEC2015	Amlodipin	AMLODIPINE	CALCIUM CHANNEL BLOCKERS	Other: arterial hypertension (MedHis no. 10)	5 mg	19May2016			MH-10
		07SEP2015	01DEC2015	Sertralin	SERTRALINE	PSYCHOANALEPTIC S	Other: Depression (AE no. 06)	50 mg	Apr2017		Yes	AE-6
		07SEP2015	01DEC2015	L-Thyrox	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyreosis	125 ug	10Jul2017	Aug2020		
		07SEP2015	01DEC2015	Traumeel creme	HOMEOPATHICS NOS	HOMEOPATHIC PREPARATION	Pain-other	as needed	03May2017	UNK		
		07SEP2015	01DEC2015	Traumeel creme	HOMEOPATHICS NOS	ALL OTHER THERAPEUTIC PRODUCTS	Pain-other	as needed	03May2017	UNK		
		07SEP2015	01DEC2015	Bupivacain	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain-other (AE no. 12)	5 ml	27Jun2018	27Jun2018		AE-12
		07SEP2015	01DEC2015	Bupivacain	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain-other (AE no. 12)	5 ml	27Jun2018	27Jun2018		AE-12
		07SEP2015	01DEC2015	Bupivacain	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain-other (AE no. 12)	5 ml	13Sep2018	13Sep2018		AE-12
		07SEP2015	01DEC2015	Bupivacain	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain-other (AE no. 12)	5 ml	13Sep2018	13Sep2018		AE-12
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 12)	80 mg	19Sep2018	19Sep2018		AE-12
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 12)	80 mg	19Sep2018	19Sep2018		AE-12
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 12)	80 mg	19Sep2018	19Sep2018		AE-12
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	VASOPROTECTIVES	Pain-other (AE no. 12)	80 mg	19Sep2018	19Sep2018		AE-12
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	NASAL PREPARATIONS	Pain-other (AE no. 12)	80 mg	19Sep2018	19Sep2018		AE-12

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
12/1201	ND plus	07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	OPHTHALMOLOGICA LS	Pain-other (AE no. 12)	80 mg	19Sep2018	19Sep2018		AE-12
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-other (AE no. 12)	80 mg	19Sep2018	19Sep2018		AE-12
		07SEP2015	01DEC2015	Azorvastatin	ATORVASTATIN	LIPID MODIFYING AGENTS	Other: Hypercholesteri naemia (MedHis no. 13)	40 mg	Jan2019		Yes	MH-13
		07SEP2015	01DEC2015	ASS	ACETYLSALICYLIC ACID	STOMATOLOGICAL PREPARATIONS	Other: prophylaxis arterial hypertension (MedHis no. 10)	100 mg	Aug2014	29Nov2015		MH-10
		07SEP2015	01DEC2015	ASS	ACETYLSALICYLIC ACID	ANTITHROMBOTIC AGENTS	Other: prophylaxis arterial hypertension (MedHis no. 10)	100 mg	Aug2014	29Nov2015		MH-10
		07SEP2015	01DEC2015	ASS	ACETYLSALICYLIC ACID	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: prophylaxis arterial hypertension (MedHis no. 10)	100 mg	Aug2014	29Nov2015		MH-10
		07SEP2015	01DEC2015	ASS	ACETYLSALICYLIC ACID	ANALGESICS	Other: prophylaxis arterial hypertension (MedHis no. 10)	100 mg	Aug2014	29Nov2015		MH-10
		07SEP2015	01DEC2015	Efient	PRASUGREL HYDROCHLORIDE	ANTITHROMBOTIC AGENTS	Other: coronary heart desease (MedHis no. 01)	10 mg	07Aug2014	31Aug2015		MH-1
		07SEP2015	01DEC2015	ASS	ACETYLSALICYLIC ACID	STOMATOLOGICAL PREPARATIONS	Other: prophylaxis arterial hypertension	100 mg	06Dec2015			

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
12/1201	ND plus	07SEP2015	01DEC2015	ASS	ACETYLSALICYLIC ACID	ANTITHROMBOTIC AGENTS	Other: prophylaxis arterial hypertension	100 mg	06Dec2015			
		07SEP2015	01DEC2015	ASS	ACETYLSALICYLIC ACID	ANALGESICS	Other: prophylaxis arterial hypertension	100 mg	06Dec2015			
		07SEP2015	01DEC2015	ASS	ACETYLSALICYLIC ACID	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: prophylaxis arterial hypertension	100 mg	06Dec2015			
		07SEP2015	01DEC2015	Cotrim forte	BACTRIM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Prophylaxis	960 mg	03Dec2015	03Dec2015		
		07SEP2015	01DEC2015	Fragmin P forte	DALTEPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Prophylaxis	5000 IU	01Dec2015	05Dec2015		
		07SEP2015	01DEC2015	Novalgin (metamizole)	METAMIZOLE SODIUM	ANALGESICS	Pain-other (AE no. 08/09)	1500	04Sep2016	Sep2016		
		07SEP2015	01DEC2015	Mepivacain 1 %	MEPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain-other (AE no. 11)	10 ml	11Jul2017	11Jul2017		AE-11
		07SEP2015	01DEC2015	Traumeel tabs	HOMEOPATHICS NOS	HOMEOPATHIC PREPARATION	Pain-other	1-1-1-1	03May2017	UNK		
		07SEP2015	01DEC2015	Traumeel tabs	HOMEOPATHICS NOS	ALL OTHER THERAPEUTIC PRODUCTS	Pain-other	1-1-1-1	03May2017	UNK		
		07SEP2015	01DEC2015	Bupivacain	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain-other (AE no. 12)	5 ml	27Jun2018	27Jun2018		AE-12
		07SEP2015	01DEC2015	Bupivacain	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain-other (AE no. 12)	5 ml	27Jun2018	27Jun2018		AE-12
		07SEP2015	01DEC2015	Bupivacain	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain-other (AE no. 12)	10 ml	19Sep2018	19Sep2018		AE-12
		07SEP2015	01DEC2015	Bupivacain	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain-other (AE no. 12)	10 ml	19Sep2018	19Sep2018		AE-12
		07SEP2015	01DEC2015	Ceftriaxon	CEFTRIAZONE SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: Prophylaxis (AE no. 12)	2 g	17Dec2018	17Dec2018		AE-12
		07SEP2015	01DEC2015	Dekristol	COLECALCIFEROL	VITAMINS	Other: Prophylaxis	20.000 IU	2019		Yes	

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
12/1201	ND plus	07SEP2015	01DEC2015	Diazepam	DIAZEPAM	MUSCLE RELAXANTS	Other: tranquinzer	5 mg	22Aug2015	11Sep2015		
		07SEP2015	01DEC2015	Diazepam	DIAZEPAM	PSYCHOLEPTICS	Other: tranquinzer	5 mg	22Aug2015	11Sep2015		
		07SEP2015	01DEC2015	Diazepam	DIAZEPAM	ANTIEPILEPTICS	Other: tranquinzer	5 mg	22Aug2015	11Sep2015		
		07SEP2015	01DEC2015	Simvahexal	SIMVASTATIN	LIPID MODIFYING AGENTS	Other: hypercholestero lemia (MedHis no. 13)	20 mg	Aug2014	UNK		MH-13
		07SEP2015	01DEC2015	Magnosanol	MAGNESIUM OXIDE	DRUGS FOR CONSTIPATION	Other: prophylaxis	300 mg	25Aug2015	11Sep2015		
		07SEP2015	01DEC2015	Magnosanol	MAGNESIUM OXIDE	DRUGS FOR ACID RELATED DISORDERS	Other: prophylaxis	300 mg	25Aug2015	11Sep2015		
		07SEP2015	01DEC2015	Magnosanol	MAGNESIUM OXIDE	MINERAL SUPPLEMENTS	Other: prophylaxis	300 mg	25Aug2015	11Sep2015		
		07SEP2015	01DEC2015	L-Thyrox	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hypothyreosis (MedHis no. 02)	125 mg	Oct2008	Jul2017		MH-2
		07SEP2015	01DEC2015	Fragmin P	DALTEPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: prophylaxis (MedHis no. 01)	2500 IE	22Aug2015	09Sep2015		MH-1
		07SEP2015	01DEC2015	Diazepam	DIAZEPAM	MUSCLE RELAXANTS	Other: tranquilizer	1.25 mg	30Nov2015	17May2016		
		07SEP2015	01DEC2015	Diazepam	DIAZEPAM	ANTIEPILEPTICS	Other: tranquilizer	1.25 mg	30Nov2015	17May2016		
		07SEP2015	01DEC2015	Diazepam	DIAZEPAM	PSYCHOLEPTICS	Other: tranquilizer	1.25 mg	30Nov2015	17May2016		
		07SEP2015	01DEC2015	Fragmin P forte	DALTEPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Prophylaxis (AE no. 05)	5000 IU	18May2016	21May2016		AE-5
		07SEP2015	01DEC2015	Clexane	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: prophylaxis (AE no. 08/09)	0.6	31Aug2016	Sep2016		
		07SEP2015	01DEC2015	Bupivacain 0.5 %	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain-other (AE no. 11)	10 ml	11Jul2017	11Jul2017		AE-11
		07SEP2015	01DEC2015	Bupivacain 0.5 %	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain-other (AE no. 11)	10 ml	11Jul2017	11Jul2017		AE-11

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
12/1201	ND plus	07SEP2015	01DEC2015	Magnesium	MAGNESIUM	MINERAL SUPPLEMENTS	Other: prophylaxis	300 mg	18May2016		Yes	
		07SEP2015	01DEC2015	Bupivacain	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain-other (AE no. 12)	5 ml	13Sep2018	13Sep2018		AE-12
		07SEP2015	01DEC2015	Bupivacain	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain-other (AE no. 12)	5 ml	13Sep2018	13Sep2018		AE-12
		07SEP2015	01DEC2015	Bupivacain	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain-other (AE no. 12)	10 ml	19Sep2018	19Sep2018		AE-12
		07SEP2015	01DEC2015	Bupivacain	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain-other (AE no. 12)	10 ml	19Sep2018	19Sep2018		AE-12
		07SEP2015	01DEC2015	Liquifilm eye drops	POLYVINYL ALCOHOL	OPHTHALMOLOGICA LS	Other: AE (AE no. 15)		07Sep2015	Sep2015		AE-15
		07SEP2015	01DEC2015	Novothyral	NOVOTHYRAL	THYROID THERAPY	Other: Hypothyreosis (MedHis no. 02)	100 ug	Aug2020		Yes	MH-2
		07SEP2015	01DEC2015	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Prophylaxis	20 mg	Aug2014		Yes	
		07SEP2015	01DEC2015	Ramipril	RAMIPRIL	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Other: arterial hypertension (MedHis no. 10)	5 mg	Aug2014	UNK		MH-10
		07SEP2015	01DEC2015	Vomex	DIMENHYDRINATE	ANTIEMETICS AND ANTINAUSEANTS	Other: concomittant to periradicular infiltration	62 mg	28Aug2015	28Aug2015		
		07SEP2015	01DEC2015	Vomex	DIMENHYDRINATE	OTHER NERVOUS SYSTEM DRUGS	Other: concomittant to periradicular infiltration	62 mg	28Aug2015	28Aug2015		
		07SEP2015	01DEC2015	Vomex	DIMENHYDRINATE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: concomittant to periradicular infiltration	62 mg	28Aug2015	28Aug2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
12/1201	ND plus	07SEP2015	01DEC2015	Ceftriaxon	CEFTRIAZONE SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: concomittant to surgical intervention	2 g	07Sep2015	07Sep2015		
		07SEP2015	01DEC2015	Tilidin	VALORON N	ANALGESICS	Pain-other (AE no. 03)	100 mg	18May2016	UNK		AE-3
		07SEP2015	01DEC2015	Diazepam	/00628301/ DIAZEPAM	ANTIEPILEPTICS	Other: Depression (AE no. 06)	2.5 mg	18May2016	May2016		AE-6
		07SEP2015	01DEC2015	Diazepam	DIAZEPAM	PSYCHOLEPTICS	Other: Depression (AE no. 06)	2.5 mg	18May2016	May2016		AE-6
		07SEP2015	01DEC2015	Diazepam	DIAZEPAM	MUSCLE RELAXANTS	Other: Depression (AE no. 06)	2.5 mg	18May2016	May2016		AE-6
		07SEP2015	01DEC2015	Fellinger-Infusio n (Novaminsulvon 2,5g, Dexamethason 4mg, amp. procaïn 17,5ml)	ANTIINFLAMMATOR Y/ANTIRHEUMATIC AGEN/90068101/ (90068101001)	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-other (AE no. 08/09)	UNK	31Aug2016	02Sep2016		
		07SEP2015	01DEC2015	L-Thyroxin	LEVOTHYROXINE SODIUM	THYROID THERAPY	Other: Hashimoto	112.5 ug	Jul2017	09Jul2017		
		07SEP2015	01DEC2015	Cetirizin 10 mg	CETIRIZINE HYDROCHLORIDE	ANTI HISTAMINES FOR SYSTEMIC USE	Other: prophylaxis in case of allergy	as needed 1 x per day	Apr2017		Yes	
		07SEP2015	01DEC2015	Cetirizin 10 mg	CETIRIZINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Other: prophylaxis in case of allergy	as needed 1 x per day	Apr2017		Yes	
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	OPHTHALMOLOGICA LS	Pain-other (AE no. 12)	40 mg	13Sep2018	13Sep2018		AE-12
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-other (AE no. 12)	40 mg	13Sep2018	13Sep2018		AE-12
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	NASAL PREPARATIONS	Pain-other (AE no. 12)	40 mg	13Sep2018	13Sep2018		AE-12
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 12)	40 mg	13Sep2018	13Sep2018		AE-12

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
12/1201	ND plus	07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	VASOPROTECTIVES	Pain-other (AE no. 12)	40 mg	13Sep2018	13Sep2018		AE-12
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 12)	40 mg	13Sep2018	13Sep2018		AE-12
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	CORTICOSTEROIDS / DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 12)	40 mg	13Sep2018	13Sep2018		AE-12
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	OPHTHALMOLOGICALS	Pain-other (AE no. 12)	80 mg	19Sep2018	19Sep2018		AE-12
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-other (AE no. 12)	80 mg	19Sep2018	19Sep2018		AE-12
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	NASAL PREPARATIONS	Pain-other (AE no. 12)	80 mg	19Sep2018	19Sep2018		AE-12
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	VASOPROTECTIVES	Pain-other (AE no. 12)	80 mg	19Sep2018	19Sep2018		AE-12
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	STOMATOLOGICAL PREPARATIONS	Pain-other (AE no. 12)	80 mg	19Sep2018	19Sep2018		AE-12
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	CORTICOSTEROIDS / DERMATOLOGICAL PREPARATIONS	Pain-other (AE no. 12)	80 mg	19Sep2018	19Sep2018		AE-12
		07SEP2015	01DEC2015	Triamcinolon	TRIAMCINOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-other (AE no. 12)	80 mg	19Sep2018	19Sep2018		AE-12
		07SEP2015	01DEC2015	Mirtazepin	MIRTAZAPINE	PSYCHOANALEPTICS	Other: Depression (AE no. 06)	30 mg	Aug2016	Apr2017		AE-6
13/1301	ND plus	07SEP2015	01DEC2015	Candecor	CANDESARTAN CILEXETIL	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	Other: Hypertension (MedHis no. 10)	8 mg	Jul2019		Yes	MH-10
		27APR2015	29JUL2015	ASS 100 mg	ACETYLSALICYLIC ACID	STOMATOLOGICAL PREPARATIONS	Other: thrombosis prophylaxis	1 x d	2012	26Apr2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
13/1301	ND plus	27APR2015	29JUL2015	ASS 100 mg	ACETYLSALICYLIC ACID	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis	1 x d	2012	26Apr2015		
		27APR2015	29JUL2015	ASS 100 mg	ACETYLSALICYLIC ACID	ANALGESICS	Other: thrombosis prophylaxis	1 x d	2012	26Apr2015		
		27APR2015	29JUL2015	ASS 100 mg	ACETYLSALICYLIC ACID	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: thrombosis prophylaxis	1 x d	2012	26Apr2015		
		27APR2015	29JUL2015	ASS 100 mg	ACETYLSALICYLIC ACID	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis	1 x d	31Jul2015		Yes	
		27APR2015	29JUL2015	ASS 100 mg	ACETYLSALICYLIC ACID	STOMATOLOGICAL PREPARATIONS	Other: thrombosis prophylaxis	1 x d	31Jul2015		Yes	
		27APR2015	29JUL2015	ASS 100 mg	ACETYLSALICYLIC ACID	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: thrombosis prophylaxis	1 x d	31Jul2015		Yes	
		27APR2015	29JUL2015	ASS 100 mg	ACETYLSALICYLIC ACID	ANALGESICS	Other: thrombosis prophylaxis	1 x d	31Jul2015		Yes	
		27APR2015	29JUL2015	Clexane 40	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis (AE no. 01 03)	1 x s.c.	20Mar2017	24Mar2017		
		27APR2015	29JUL2015	Monoemborex 3000 iE	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: Thrombosis prophylaxis	0-0-1	26Apr2015	May2015		
		27APR2015	29JUL2015	Etoricoxib 120	ETORICOXIB	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Other: AE 06 (AE no. 05)	1/0/0	Jan2020	Feb2020		AE-5
		27APR2015	29JUL2015	Monoemborex 3000 iE	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: prophylaxis	1 x d sc	28Jul2015	30Jul2015		
		27APR2015	29JUL2015	Zofran	ONDANSETRON	ANTIEMETICS AND ANTINAUSEANTS	Other: antiemeticum	single infusion	27Apr2015	27Apr2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
13/1301	ND plus	27APR2015	29JUL2015	Monoemborex 3000 iE	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: prophylaxis	1 x d sc	26Apr2015	03May2015		
		27APR2015	29JUL2015	ASS 100 mg	ACETYLSALICYLIC ACID	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis	1 x d	04May2015	26Jul2015		
		27APR2015	29JUL2015	ASS 100 mg	ACETYLSALICYLIC ACID	STOMATOLOGICAL PREPARATIONS	Other: thrombosis prophylaxis	1 x d	04May2015	26Jul2015		
		27APR2015	29JUL2015	ASS 100 mg	ACETYLSALICYLIC ACID	ANALGESICS	Other: thrombosis prophylaxis	1 x d	04May2015	26Jul2015		
		27APR2015	29JUL2015	ASS 100 mg	ACETYLSALICYLIC ACID	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: thrombosis prophylaxis	1 x d	04May2015	26Jul2015		
13/1302	ND plus	12MAY2015	29JUL2015	Ramipril 5 mg	RAMIPRIL	AGENTS ACTING ON THE RENIN-ANGIOTENS IN SYSTEM	Other: blood pressure	1-0-0	2010		Yes	
		12MAY2015	29JUL2015	orthoton 750 mg	METHOCARBAMOL	MUSCLE RELAXANTS	Other: muscle relax	2-0-0	14May2015	14May2015		
		12MAY2015	29JUL2015	Mydocalm 50 ml	TOLPERISONE HYDROCHLORIDE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Other: muscle relaxant	0-0-0-1	14May2015	16May2015		
		12MAY2015	29JUL2015	Mydocalm 50 ml	TOLPERISONE HYDROCHLORIDE	MUSCLE RELAXANTS	Other: muscle relaxant	0-0-0-1	14May2015	16May2015		
		12MAY2015	29JUL2015	Monoemborex 3000 iE	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis	1 x d sc	29Jul2015	30Jul2015		
		12MAY2015	29JUL2015	Metoprolol 47.5	METOPROLOL	BETA BLOCKING AGENTS	Other: blood pressure	1-0-0	2010		Yes	
		12MAY2015	29JUL2015	Pantozol 40 mg (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: protection	1-0-0	05May2015	16May2015		
		12MAY2015	29JUL2015	Obstinol M	PARAFFIN, LIQUID	DRUGS FOR CONSTIPATION	Other: obstipation	45 ml, 2 x d	08May2015	16May2015		

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
13/1302	ND plus	12MAY2015	29JUL2015	Obstinol M	PARAFFIN, LIQUID	HOMEOPATHIC PREPARATION	Other: obstipation	45 ml, 2 x d	08May2015	16May2015	
		12MAY2015	29JUL2015	Obstinol M	PARAFFIN, LIQUID	OPHTHALMOLOGICA LS	Other: obstipation	45 ml, 2 x d	08May2015	16May2015	
		12MAY2015	29JUL2015	Obstinol M	PARAFFIN, LIQUID	OTOLOGICALS	Other: obstipation	45 ml, 2 x d	08May2015	16May2015	
		12MAY2015	29JUL2015	Obstinol M	PARAFFIN, LIQUID	EMOLLIENTS AND PROTECTIVES	Other: obstipation	45 ml, 2 x d	08May2015	16May2015	
		12MAY2015	29JUL2015	Orthoton 750 mg	METHOCARBAMOL	MUSCLE RELAXANTS	Other: muscle relax	2-2-2	05May2015	13May2015	
		12MAY2015	29JUL2015	Cefuroxin 1.5 mg	CEFUROXIME SODIUM	OPHTHALMOLOGICA LS	Other: intraop antibiotic	1.5 mg	29Jul2015	29Jul2015	
		12MAY2015	29JUL2015	Cefuroxin 1.5 mg	CEFUROXIME SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: intraop antibiotic	1.5 mg	29Jul2015	29Jul2015	
		12MAY2015	29JUL2015	Clexane 4000 iE	ENOXAPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: prophylaxis	1xd s.c.	06May2015	15May2015	
13/1303	SC	29JUN2015	-	Cefuroxim 1.5 mg	CEFUROXIME	ANTIBACTERIALS FOR SYSTEMIC USE	Other: intra-op antibiotic	1.5 mg	29Jun2015	29Jun2015	
		29JUN2015	-	Cefuroxim 1.5 mg	CEFUROXIME	OPHTHALMOLOGICA LS	Other: intra-op antibiotic	1.5 mg	29Jun2015	29Jun2015	
		29JUN2015	-	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: prophylaxis	40 mg, 1 x d	23Jun2015	02Jul2015	
		29JUN2015	-	Monoembolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis	3000 iE 1 x d sc	28Jun2015	02Jul2015	
		29JUN2015	-	Mono-Embolex	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis	3000 IE/d s.c.	25Jun2015	25Jun2015	
13/1304	ND basic	02JUL2015	18SEP2015	Vitamin B-Komplex	TRINEURIN	VITAMINS	Other: neurologic	0-1-0	Oct2015	01Apr2016	

/00499701/

Listing 16.2.1.11: Previous and concomitant medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
13/1304	ND basic	02JUL2015	18SEP2015	Monoemborex 3000 iE	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis	1 x d sc	01Jul2015	04Jul2015		
		02JUL2015	18SEP2015	magnesium	MAGNESIUM	MINERAL SUPPLEMENTS	Other: muscle hardening (AE no. 01)	1x300 mg/d	14Sep2016		Yes	AE-1
		02JUL2015	18SEP2015	Metoclopramid 10 mg	METOCLOPRAMIDE	DRUGS FOR FUNCTIONAL GASTROINTESTINA L DISORDERS	Other: antiemetic	single infusion	02Jul2015	02Jul2015		
		02JUL2015	18SEP2015	Pantozol 40 mg (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Other: Stomac protection	1/0/0	21Jun2015	09Jul2015		
		02JUL2015	18SEP2015	Keltican forte (Uridinmonophosph at+Vitamin B12+Folic acid)	KELTICAN /06870301/	ANTIANEMIC PREPARATIONS	Other: neuronal drug	1 x d	15Sep2015	12Dec2015		
		02JUL2015	18SEP2015	Cefuroxin 1.5 g	CEFUROXIME SODIUM	OPHTHALMOLOGICA LS	Other: intra op antibiotic	1 x d	02Jul2015	02Jul2015		
		02JUL2015	18SEP2015	Cefuroxin 1.5 g	CEFUROXIME SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: intra op antibiotic	1 x d	02Jul2015	02Jul2015		
		02JUL2015	18SEP2015	Monoemborex 3000 iE	CERTOPARIN SODIUM	ANTITHROMBOTIC AGENTS	Other: thrombosis prophylaxis	1 x d sc	22Jun2015	22Jun2015		
13/1305	ND plus	15OCT2015	-	Cefuroxin	CEFUROXIME SODIUM	ANTIBACTERIALS FOR SYSTEMIC USE	Other: intra op antibiotic	1.5 g	15Oct2015	15Oct2015		
		15OCT2015	-	Cefuroxin	CEFUROXIME SODIUM	OPHTHALMOLOGICA LS	Other: intra op antibiotic	1.5 g	15Oct2015	15Oct2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0103	ND basic	18OCT2012	15JAN2013	Diclobene	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain	2 X 100 MG	17Oct2012	21Oct2012	
		18OCT2012	15JAN2013	Diclobene	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain	2 X 100 MG	17Oct2012	21Oct2012	
		18OCT2012	15JAN2013	Diclobene	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain	2 X 100 MG	17Oct2012	21Oct2012	
		18OCT2012	15JAN2013	Diclobene	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	2 X 100 MG	17Oct2012	21Oct2012	
		18OCT2012	15JAN2013	Diclobene	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	2 X 100 MG	17Oct2012	21Oct2012	
		18OCT2012	15JAN2013	Diclobene	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain	2 X 100 MG	17Oct2012	21Oct2012	
		18OCT2012	15JAN2013	Perfalgan	PARACETAMOL	ANALGESICS	Pain	2 G	18Oct2012	18Oct2012	
		18OCT2012	15JAN2013	Saroten	AMITRIPTYLINE HYDROCHLORIDE	ANALGESICS	Pain	25 MG	25Mar2013	10May2013	
		18OCT2012	15JAN2013	Saroten	AMITRIPTYLINE HYDROCHLORIDE	PSYCHOANALEPTIC S	Pain	25 MG	25Mar2013	10May2013	
		18OCT2012	15JAN2013	Perfalgan	PARACETAMOL	ANALGESICS	Pain	1 G	17Oct2012	17Oct2012	
		18OCT2012	15JAN2013	Perfalgan	PARACETAMOL	ANALGESICS	Pain	1 G	19Oct2012	19Oct2012	
		18OCT2012	15JAN2013	Diclobene	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	50 MG	14Jan2013	17Jan2013	
		18OCT2012	15JAN2013	Diclobene	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	50 MG	14Jan2013	17Jan2013	
		18OCT2012	15JAN2013	Diclobene	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain	50 MG	14Jan2013	17Jan2013	
		18OCT2012	15JAN2013	Diclobene	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain	50 MG	14Jan2013	17Jan2013	
		18OCT2012	15JAN2013	Diclobene	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain	50 MG	14Jan2013	17Jan2013	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0103	ND basic	18OCT2012	15JAN2013	Diclobene	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain	50 MG	14Jan2013	17Jan2013	
		18OCT2012	15JAN2013	Dipidolon	PIRITRAMIDE	ANALGESICS	Pain	7.5 MG 1 X	17Oct2012	18Oct2012	
		18OCT2012	15JAN2013	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain	2 X 500 MG	14Jan2013	15Jan2013	
		18OCT2012	15JAN2013	Diclobene	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	4 X 100 MG IF NEEDED	25Jan2013	Aug2013	
		18OCT2012	15JAN2013	Diclobene	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	4 X 100 MG IF NEEDED	25Jan2013	Aug2013	
		18OCT2012	15JAN2013	Diclobene	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain	4 X 100 MG IF NEEDED	25Jan2013	Aug2013	
		18OCT2012	15JAN2013	Diclobene	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain	4 X 100 MG IF NEEDED	25Jan2013	Aug2013	
		18OCT2012	15JAN2013	Diclobene	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain	4 X 100 MG IF NEEDED	25Jan2013	Aug2013	
		18OCT2012	15JAN2013	Diclobene	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain	4 X 100 MG IF NEEDED	25Jan2013	Aug2013	
		18OCT2012	15JAN2013	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain	2 X 100 MG	04Feb2013	Feb2013	
		18OCT2012	15JAN2013	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain	4 X 500 MG	16Jan2013	17Jan2013	
		18OCT2012	15JAN2013	Dipidolon	PIRITRAMIDE	ANALGESICS	Pain	1 X 7.5 MG	17Feb2013	17Feb2013	
01/0104	ND basic	24OCT2012	22JAN2013	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1200 MG PO	25Oct2012	27Oct2012	
		24OCT2012	22JAN2013	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1200 MG PO	25Oct2012	27Oct2012	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0104	ND basic	24OCT2012	22JAN2013	Thomapyrin (Acetylsalicylaci d, coffein, paracetamol)	THOMAPYRIN N	ANALGESICS	Pain	2 X 1 TBL.	25Dec2013	25Dec2013	
		24OCT2012	22JAN2013	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain	2000 MG PO	25Oct2012	26Oct2012	
		24OCT2012	22JAN2013	Thomapyrin (Acetylsalicylaci d, coffein, paracetamol)	THOMAPYRIN N	ANALGESICS	Pain	2 X 1 TBL.	02Jan2014	02Jan2014	
		24OCT2012	22JAN2013	Dipidolor	PIRITRAMIDE	ANALGESICS	Pain	1 ML SC	24Oct2012	24Oct2012	
		24OCT2012	22JAN2013	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1200 MG PO	03Nov2012	08Nov2012	
		24OCT2012	22JAN2013	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1200 MG PO	03Nov2012	08Nov2012	
		24OCT2012	22JAN2013	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	800 MG PO	22Jan2013	23Jan2013	
		24OCT2012	22JAN2013	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	800 MG PO	22Jan2013	23Jan2013	
		24OCT2012	22JAN2013	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1200 MG IF NEEDED	25May2013	31Jul2013	
		24OCT2012	22JAN2013	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1200 MG IF NEEDED	25May2013	31Jul2013	
		24OCT2012	22JAN2013	Myolastan	TETRAZEPAM	MUSCLE RELAXANTS	Pain	100 MG IF NEEDED	25May2013	31Jul2013	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0106	ND plus	28NOV2012	19FEB2013	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	400 MG IF NEEDED	02Dec2012	03Dec2012		
		28NOV2012	19FEB2013	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	400 MG IF NEEDED	02Dec2012	03Dec2012		
		28NOV2012	19FEB2013	PROXEN (NAPROXEN)	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain - other	500 MG	30Dec2014	30Dec2014		
		28NOV2012	19FEB2013	PROXEN (NAPROXEN)	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain - other	500 MG	30Dec2014	30Dec2014		
		28NOV2012	19FEB2013	PROXEN (NAPROXEN)	NAPROXEN	OTHER GYNECOLOGICALS	Pain - other	500 MG	30Dec2014	30Dec2014		
		28NOV2012	19FEB2013	PROXEN (NAPROXEN)	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Pain - other	500 MG	30Dec2014	30Dec2014		
		28NOV2012	19FEB2013	PROXEN (NAPROXEN)	NAPROXEN	OPHTHALMOLOGICA LS	Pain - other	500 MG	30Dec2014	30Dec2014		
		28NOV2012	19FEB2013	Novalgine (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain	2000 MG	28Nov2012	02Dec2012		
		28NOV2012	19FEB2013	PROXEN (NAPROXEN)	NAPROXEN	OPHTHALMOLOGICA LS	Pain - other	500 MG IF NEEDED	01Apr2015		Yes	
		28NOV2012	19FEB2013	PROXEN (NAPROXEN)	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Pain - other	500 MG IF NEEDED	01Apr2015		Yes	
		28NOV2012	19FEB2013	PROXEN (NAPROXEN)	NAPROXEN	OTHER GYNECOLOGICALS	Pain - other	500 MG IF NEEDED	01Apr2015		Yes	
		28NOV2012	19FEB2013	PROXEN (NAPROXEN)	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain - other	500 MG IF NEEDED	01Apr2015		Yes	
		28NOV2012	19FEB2013	PROXEN (NAPROXEN)	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain - other	500 MG IF NEEDED	01Apr2015		Yes	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0106	ND plus	28NOV2012	19FEB2013	Proxen (Naproxen)	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1000 MG	03Feb2013	04Feb2013		
		28NOV2012	19FEB2013	Proxen (Naproxen)	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1000 MG	03Feb2013	04Feb2013		
		28NOV2012	19FEB2013	Proxen (Naproxen)	NAPROXEN	OTHER GYNECOLOGICALS	Pain	1000 MG	03Feb2013	04Feb2013		
		28NOV2012	19FEB2013	Proxen (Naproxen)	NAPROXEN	OPHTHALMOLOGICA LS	Pain	1000 MG	03Feb2013	04Feb2013		
		28NOV2012	19FEB2013	Proxen (Naproxen)	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Pain	1000 MG	03Feb2013	04Feb2013		
		28NOV2012	19FEB2013	Novalgine (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain	2000 MG	19Feb2013	21Feb2013		
01/0107	ND plus	09JAN2013	09APR2013	Myolastan	TETRAZEPAM	MUSCLE RELAXANTS	Pain	50 MG 1X	10Jan2013	14Jan2013		
		09JAN2013	09APR2013	Diclobene	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	150 MG	10Jan2013	14Jan2013		
		09JAN2013	09APR2013	Diclobene	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	150 MG	10Jan2013	14Jan2013		
		09JAN2013	09APR2013	Diclobene	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain	150 MG	10Jan2013	14Jan2013		
		09JAN2013	09APR2013	Diclobene	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain	150 MG	10Jan2013	14Jan2013		
		09JAN2013	09APR2013	Diclobene	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain	150 MG	10Jan2013	14Jan2013		
		09JAN2013	09APR2013	Diclobene	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain	150 MG	10Jan2013	14Jan2013		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0107	ND plus	09JAN2013	09APR2013	seractil forte	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	800 MG	08Apr2013	11Apr2013		
		09JAN2013	09APR2013	seractil forte	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	800 MG	08Apr2013	11Apr2013		
		09JAN2013	09APR2013	Perfalgan	PARACETAMOL	ANALGESICS	Pain	1 G IF NEEDED	09Jan2013	14Jan2013		
		09JAN2013	09APR2013	Dipidolor	PIRITRAMIDE	ANALGESICS	Pain	7.5 MG IF NEEDED	09Jan2013	14Jan2013		
		09JAN2013	09APR2013	Perfalgan	PARACETAMOL	ANALGESICS	Pain	1 G 1X	09Apr2013	09Apr2013		
01/0108	ND plus	10JAN2013	16APR2013	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	800 MG	09Jan2013	13Jan2013		
		10JAN2013	16APR2013	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	800 MG	09Jan2013	13Jan2013		
		10JAN2013	16APR2013	Aspirin	ACETYLSALICYLIC ACID	ANALGESICS	Pain	1000 MG IF NEEDED	28Nov2013		Yes	
		10JAN2013	16APR2013	Aspirin	ACETYLSALICYLIC ACID	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1000 MG IF NEEDED	28Nov2013		Yes	
		10JAN2013	16APR2013	Aspirin	ACETYLSALICYLIC ACID	ANTITHROMBOTIC AGENTS	Pain	1000 MG IF NEEDED	28Nov2013		Yes	
		10JAN2013	16APR2013	Aspirin	ACETYLSALICYLIC ACID	STOMATOLOGICAL PREPARATIONS	Pain	1000 MG IF NEEDED	28Nov2013		Yes	
		10JAN2013	16APR2013	Mexalen	PARACETAMOL	ANALGESICS	Pain	1500 MG	10Jan2013	13Jan2013		
		10JAN2013	16APR2013	Perfalgan	PARACETAMOL	ANALGESICS	Pain	1 G X1	16Apr2013	16Apr2013		
01/0110	ND basic	24JAN2013	23APR2013	Mexalen	PARACETAMOL	ANALGESICS	Pain	500 MG X1	17Apr2013	17Apr2013		
		24JAN2013	23APR2013	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain	37.5 MG (3 X 12.5)	15Mar2013	30Mar2013		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0110	ND basic	24JAN2013	23APR2013	Diclobene	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	50 MG-150 MG IF NEEDED	22Jan2013		Yes	
		24JAN2013	23APR2013	Diclobene	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	50 MG-150 MG IF NEEDED	22Jan2013		Yes	
		24JAN2013	23APR2013	Diclobene	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain	50 MG-150 MG IF NEEDED	22Jan2013		Yes	
		24JAN2013	23APR2013	Diclobene	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain	50 MG-150 MG IF NEEDED	22Jan2013		Yes	
		24JAN2013	23APR2013	Diclobene	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain	50 MG-150 MG IF NEEDED	22Jan2013		Yes	
		24JAN2013	23APR2013	Diclobene	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain	50 MG-150 MG IF NEEDED	22Jan2013		Yes	
		24JAN2013	23APR2013	Dipidolon	PIRITRAMIDE	ANALGESICS	Pain	7.5 MG	22Jan2013	23Jan2013		
		24JAN2013	23APR2013	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1200 MG	22Apr2013	27Apr2013		
		24JAN2013	23APR2013	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1200 MG	22Apr2013	27Apr2013		
		24JAN2013	23APR2013	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain	1500 MG	24Apr2013	25Apr2013		
01/0111	ND plus	24JAN2013	23APR2013	Vendal	MORPHINE HYDROCHLORIDE	ANALGESICS	Pain	5 MG 1X	24Apr2013	24Apr2013		
		12MAR2013	11JUN2013	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	400 MG 1-3 IF NEEDED	13Mar2013	10Jul2013		
		12MAR2013	11JUN2013	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	400 MG 1-3 IF NEEDED	13Mar2013	10Jul2013		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0112	ND basic	26MAR2013	-	Diclobene	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain	150 MG AS NEEDED	27Mar2013		Yes	
		26MAR2013	-	Diclobene	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain	150 MG AS NEEDED	27Mar2013		Yes	
		26MAR2013	-	Diclobene	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain	150 MG AS NEEDED	27Mar2013		Yes	
		26MAR2013	-	Diclobene	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	150 MG AS NEEDED	27Mar2013		Yes	
		26MAR2013	-	Diclobene	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	150 MG AS NEEDED	27Mar2013		Yes	
		26MAR2013	-	Diclobene	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain	150 MG AS NEEDED	27Mar2013		Yes	
		26MAR2013	-	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain	1500 MG	27Mar2013	29Mar2013		
01/0113	ND basic	23MAY2013	06AUG2013	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	400 MG	25May2013	25May2013		
		23MAY2013	06AUG2013	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	400 MG	25May2013	25May2013		
		23MAY2013	06AUG2013	NEODOLPASSE	NEODOLPASSE	MUSCLE RELAXANTS	Pain	250 ML	14Jul2014	25Jul2014		
		23MAY2013	06AUG2013	Voltaren	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	300 MG ON DEMAND	22May2013	24May2013		
		23MAY2013	06AUG2013	Voltaren	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	300 MG ON DEMAND	22May2013	24May2013		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0113	ND basic	23MAY2013	06AUG2013	Voltaren	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain	300 MG ON DEMAND	22May2013	24May2013		
		23MAY2013	06AUG2013	Voltaren	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain	300 MG ON DEMAND	22May2013	24May2013		
		23MAY2013	06AUG2013	Voltaren	DICLOFENAC	OPHTHALMOLOGICA LS	Pain	300 MG ON DEMAND	22May2013	24May2013		
		23MAY2013	06AUG2013	Voltaren	DICLOFENAC	THROAT PREPARATIONS	Pain	300 MG ON DEMAND	22May2013	24May2013		
		23MAY2013	06AUG2013	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	800 MG	05Aug2014	20Aug2014		
		23MAY2013	06AUG2013	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	800 MG	05Aug2014	20Aug2014		
		23MAY2013	06AUG2013	Vendal	MORPHINE HYDROCHLORIDE	ANALGESICS	Pain	2.5 MG	26May2013	26May2013		
		23MAY2013	06AUG2013	TRAMAL	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain	50 MG	14Jul2014	25Jul2014		
		23MAY2013	06AUG2013	Diclobene	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	150 MG ON DEMAND	06Aug2013	06Aug2013		
		23MAY2013	06AUG2013	Diclobene	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	150 MG ON DEMAND	06Aug2013	06Aug2013		
		23MAY2013	06AUG2013	Diclobene	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain	150 MG ON DEMAND	06Aug2013	06Aug2013		
		23MAY2013	06AUG2013	Diclobene	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain	150 MG ON DEMAND	06Aug2013	06Aug2013		
		23MAY2013	06AUG2013	Diclobene	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain	150 MG ON DEMAND	06Aug2013	06Aug2013		
		23MAY2013	06AUG2013	Diclobene	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain	150 MG ON DEMAND	06Aug2013	06Aug2013		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0114	ND basic	11JUN2013	11SEP2013	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	(400 MG 3 X) 1200 MG	09Jun2013	14Jun2013		
		11JUN2013	11SEP2013	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	(400 MG 3 X) 1200 MG	09Jun2013	14Jun2013		
		11JUN2013	11SEP2013	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	400 MG 1-2 X ON DEMAND	15Jun2013		Yes	
		11JUN2013	11SEP2013	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	400 MG 1-2 X ON DEMAND	15Jun2013		Yes	
		11JUN2013	11SEP2013	Mexalen	PARACETAMOL	ANALGESICS	Pain	500 MG ON DEMAND	10Aug2013		Yes	
		11JUN2013	11SEP2013	Novalgin/metamizole	METAMIZOLE SODIUM	ANALGESICS	Pain	1500 MG (500 MG 3 X)	09Jun2013	15Jun2013		
		11JUN2013	11SEP2013	Dipidolon	PIRITRAMIDE	ANALGESICS	Pain	7.5 MG	09Jun2013	11Jun2013		
01/0115	ND plus	12JUN2013	17SEP2013	Neurobion forte (B1 100mg, B6 200 mg, B12 200ug)	VITAMEDIN INTRAVENOUS	VITAMINS	Pain	3 X TBL/DAY	12Jun2013	15Jun2013		
		12JUN2013	17SEP2013	Diclobene ret	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain	200 MG IF NEEDED	10Jun2013	20Jun2013		
		12JUN2013	17SEP2013	Diclobene ret	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	200 MG IF NEEDED	10Jun2013	20Jun2013		
		12JUN2013	17SEP2013	Diclobene ret	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN THROAT PREPARATIONS	Pain	200 MG IF NEEDED	10Jun2013	20Jun2013		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo ing? MH/AE
01/0115	ND plus	12JUN2013	17SEP2013	Diclobene ret	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain	200 MG IF NEEDED	10Jun2013	20Jun2013	
		12JUN2013	17SEP2013	Diclobene ret	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain	200 MG IF NEEDED	10Jun2013	20Jun2013	
		12JUN2013	17SEP2013	Dolobene	DOLOBENE	VASOPROTECTIVES	Pain	100 MG	11Jun2013	12Jun2013	
		12JUN2013	17SEP2013	Dolobene	DOLOBENE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	100 MG	11Jun2013	12Jun2013	
		12JUN2013	17SEP2013	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1200 MG IF NEEDED	17Sep2013	20Sep2013	
		12JUN2013	17SEP2013	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1200 MG IF NEEDED	17Sep2013	20Sep2013	
01/0116	ND basic	18JUN2013	-	Diclobene	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain	200 MG ON DEMAND	17Jun2013	20Jun2013	
		18JUN2013	-	Diclobene	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	200 MG ON DEMAND	17Jun2013	20Jun2013	
		18JUN2013	-	Diclobene	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	200 MG ON DEMAND	17Jun2013	20Jun2013	
		18JUN2013	-	Diclobene	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain	200 MG ON DEMAND	17Jun2013	20Jun2013	
		18JUN2013	-	Diclobene	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain	200 MG ON DEMAND	17Jun2013	20Jun2013	
		18JUN2013	-	Diclobene	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain	200 MG ON DEMAND	17Jun2013	20Jun2013	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0118	ND plus	10JUL2013	08OCT2013	Seractil forte	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1200 MG IF NEEDED	10Jul2013	14Jul2013		
		10JUL2013	08OCT2013	Seractil forte	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1200 MG IF NEEDED	10Jul2013	14Jul2013		
		10JUL2013	08OCT2013	Neodolpasse infusion	NEODOLPASSE	MUSCLE RELAXANTS	Pain	250 ML	02Mar2014	12Mar2014		
		10JUL2013	08OCT2013	VOLON A (Triamcinolon, Acetonid)	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain	40 MG	08Jun2016	08Jun2016		
		10JUL2013	08OCT2013	VOLON A (Triamcinolon, Acetonid)	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain	40 MG	08Jun2016	08Jun2016		
		10JUL2013	08OCT2013	VOLON A (Triamcinolon, Acetonid)	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain	40 MG	08Jun2016	08Jun2016		
		10JUL2013	08OCT2013	VOLON A (Triamcinolon, Acetonid)	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICA LS	Pain	40 MG	08Jun2016	08Jun2016		
		10JUL2013	08OCT2013	VOLON A (Triamcinolon, Acetonid)	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Pain	40 MG	08Jun2016	08Jun2016		
		10JUL2013	08OCT2013	VOLON A (Triamcinolon, Acetonid)	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Pain	40 MG	08Jun2016	08Jun2016		
		10JUL2013	08OCT2013	VOLON A (Triamcinolon, Acetonid)	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Pain	40 MG	08Jun2016	08Jun2016		
		10JUL2013	08OCT2013	Novalgine/Metamizo le	METAMIZOLE SODIUM	ANALGESICS	Pain	1500 MG	10Jul2013	11Jul2013		
		10JUL2013	08OCT2013	Transtec plaster	BUPRENORPHINE	ANALGESICS	Pain	35 UG/H	20Sep2015		Yes	
		10JUL2013	08OCT2013	Transtec plaster	BUPRENORPHINE	OTHER NERVOUS SYSTEM DRUGS	Pain	35 UG/H	20Sep2015		Yes	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0118	ND plus	10JUL2013	08OCT2013	Proxen/Naprobene	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1000 MG IF NEEDED	09Jul2013		Yes	
		10JUL2013	08OCT2013	Proxen/Naprobene	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1000 MG IF NEEDED	09Jul2013		Yes	
		10JUL2013	08OCT2013	Proxen/Naprobene	NAPROXEN	OTHER GYNECOLOGICALS	Pain	1000 MG IF NEEDED	09Jul2013		Yes	
		10JUL2013	08OCT2013	Proxen/Naprobene	NAPROXEN	OPHTHALMOLOGICA LS	Pain	1000 MG IF NEEDED	09Jul2013		Yes	
		10JUL2013	08OCT2013	Proxen/Naprobene	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Pain	1000 MG IF NEEDED	09Jul2013		Yes	
		10JUL2013	08OCT2013	Novalgine (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain	1500 MG	09Jul2014		Yes	
		10JUL2013	08OCT2013	Dipidolor	PIRITRAMIDE	ANALGESICS	Pain	1 ML=7.5 MG IF NEEDED	08Jul2013	10Jul2013		
		10JUL2013	08OCT2013	Hydal	HYDROMORPHONE HYDROCHLORIDE	ANALGESICS	Pain	4 MG	Apr2014		Yes	
		10JUL2013	08OCT2013	Seractil forte	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	400 MG	07Oct2013	11Oct2013		
		10JUL2013	08OCT2013	Seractil forte	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	400 MG	07Oct2013	11Oct2013		
		10JUL2013	08OCT2013	Buccain PRT	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain	1 X 4 ML PERIRADICULAR	31Mar2014	31Mar2014		
		10JUL2013	08OCT2013	Buccain PRT	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain	1 X 4 ML PERIRADICULAR	31Mar2014	31Mar2014		
		10JUL2013	08OCT2013	Dipidolor	PIRITRAMIDE	ANALGESICS	Pain	1 ML=7.5 MG	08Oct2013	09Oct2013		
		10JUL2013	08OCT2013	BUCAIN 0.25 % (INFILTRATION)	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain	2 ML	27Aug2015	27Aug2015		
		10JUL2013	08OCT2013	BUCAIN 0.25 % (INFILTRATION)	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain	2 ML	27Aug2015	27Aug2015		
		10JUL2013	08OCT2013	Neodolpasse infusion	NEODOLPASSE	MUSCLE RELAXANTS	Pain	250 ML	25Nov2013	29Nov2013		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0118	ND plus	10JUL2013	08OCT2013	VOLON A (INFILTRATION) (Tr iamcinolon, Acetonid)	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain	40 MG	27Aug2015	27Aug2015		
		10JUL2013	08OCT2013	VOLON A (INFILTRATION) (Tr iamcinolon, Acetonid)	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain	40 MG	27Aug2015	27Aug2015		
		10JUL2013	08OCT2013	VOLON A (INFILTRATION) (Tr iamcinolon, Acetonid)	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain	40 MG	27Aug2015	27Aug2015		
		10JUL2013	08OCT2013	VOLON A (INFILTRATION) (Tr iamcinolon, Acetonid)	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICA LS	Pain	40 MG	27Aug2015	27Aug2015		
		10JUL2013	08OCT2013	VOLON A (INFILTRATION) (Tr iamcinolon, Acetonid)	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Pain	40 MG	27Aug2015	27Aug2015		
		10JUL2013	08OCT2013	VOLON A (INFILTRATION) (Tr iamcinolon, Acetonid)	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Pain	40 MG	27Aug2015	27Aug2015		
		10JUL2013	08OCT2013	VOLON A (INFILTRATION) (Tr iamcinolon, Acetonid)	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Pain	40 MG	27Aug2015	27Aug2015		
		10JUL2013	08OCT2013	BUCAIN 0.25 %	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain	1 ML	08Jun2016	08Jun2016		
		10JUL2013	08OCT2013	BUCAIN 0.25 %	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain	1 ML	08Jun2016	08Jun2016		
01/0119	ND basic	23JUL2013	15OCT2013	MEXALEN	PARACETAMOL	ANALGESICS	Pain	1500 MG IF NEEDED	22Jul2013	27Jul2013		
		23JUL2013	15OCT2013	Thomapyrin (Acetylsalicylaci d, Coffein, Paracetamol)	THOMAPYRIN N	ANALGESICS	Pain	1 TABL IF NEEDED	Jan2014		Yes	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0119	ND basic	23JUL2013	15OCT2013	PERFALGAN	PARACETAMOL	ANALGESICS	Pain	1000 MG	15Oct2013	15Oct2013	
		23JUL2013	15OCT2013	MEXALEN	PARACETAMOL	ANALGESICS	Pain	1500 MG IF NEEDED	15Oct2013	18Oct2013	
		23JUL2013	15OCT2013	NEUROBION FORTE (Vit B)	VITAMEDIN INTRAVENOUS	VITAMINS	Pain	3 X TABLETS DAILY	25Oct2013	26Oct2013	
01/0121	ND plus	15OCT2013	14JAN2014	Perfalgan	PARACETAMOL	ANALGESICS	Pain	10 MG	15Oct2013	15Oct2013	
		15OCT2013	14JAN2014	Diclobene	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	150 MG IF NEEDED	16Oct2013	19Oct2013	
		15OCT2013	14JAN2014	Diclobene	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	150 MG IF NEEDED	16Oct2013	19Oct2013	
		15OCT2013	14JAN2014	Diclobene	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain	150 MG IF NEEDED	16Oct2013	19Oct2013	
		15OCT2013	14JAN2014	Diclobene	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain	150 MG IF NEEDED	16Oct2013	19Oct2013	
		15OCT2013	14JAN2014	Diclobene	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain	150 MG IF NEEDED	16Oct2013	19Oct2013	
		15OCT2013	14JAN2014	Diclobene	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain	150 MG IF NEEDED	16Oct2013	19Oct2013	
		15OCT2013	14JAN2014	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain	1500 MG	16Oct2013	19Oct2013	
		15OCT2013	14JAN2014	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1200 MG IF NEEDED	14Jan2014	16Jan2014	
01/0122	ND plus	26SEP2013	17DEC2013	Novalgin - Metamizol Liquid	METAMIZOLE SODIUM	ANALGESICS	Pain	25 DROPS	03Mar2014	09Mar2014	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0122	ND plus	26SEP2013	17DEC2013	VIMOVO	VIMOVO	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1000 MG	11Jun2016	15Jun2016	
		26SEP2013	17DEC2013	TRAMAL	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain	100 MG	11Jun2016	15Jun2016	
01/0123	ND plus	16SEP2014	19DEC2014	DICLOBENE	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	100 mg if needed	01Sep2013	14Sep2014	
		16SEP2014	19DEC2014	DICLOBENE	DICLOFENAC SODIUM	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	100 mg if needed	01Sep2013	14Sep2014	
		16SEP2014	19DEC2014	DICLOBENE	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted	100 mg if needed	01Sep2013	14Sep2014	
		16SEP2014	19DEC2014	DICLOBENE	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain-study-rela ted	100 mg if needed	01Sep2013	14Sep2014	
		16SEP2014	19DEC2014	DICLOBENE	DICLOFENAC SODIUM	OPHTHALMOLOGICA LS	Pain-study-rela ted	100 mg if needed	01Sep2013	14Sep2014	
		16SEP2014	19DEC2014	DICLOBENE	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	100 mg if needed	01Sep2013	14Sep2014	
		16SEP2014	19DEC2014	PERFALGAN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1000 mg	16Sep2014	16Sep2014	
		16SEP2014	19DEC2014	VENDAL	MORPHINE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	5 mg	16Sep2014	17Sep2014	
01/0124	ND plus	06NOV2014	-	RATIODOLOR AKUT	IBUPROFEN LYSINATE	OTHER GYNECOLOGICALS	Pain-study-rela ted	1-2x 400 mg	10Sep2014	01Oct2014	
		06NOV2014	-	RATIODOLOR AKUT	IBUPROFEN LYSINATE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1-2x 400 mg	10Sep2014	01Oct2014	
		06NOV2014	-	RATIODOLOR AKUT	IBUPROFEN LYSINATE	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1-2x 400 mg	10Sep2014	01Oct2014	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0124	ND plus	06NOV2014	-	RATIODOLOR AKUT	IBUPROFEN LYSINATE	CARDIAC THERAPY	Pain-study-rela ted	1-2x 400 mg	10Sep2014	01Oct2014	
		06NOV2014	-	SERACTIL FORTE	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	800 mg	01Oct2014	01Oct2014	
		06NOV2014	-	SERACTIL FORTE	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	800 mg	01Oct2014	01Oct2014	
01/0125	SC	07OCT2014	-	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	800 mg	03Oct2014	19Oct2014	
		07OCT2014	-	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	800 mg	03Oct2014	19Oct2014	
		07OCT2014	-	DIPIDOLOR	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	7.5 mg	07Oct2014	08Oct2014	
		07OCT2014	-	SERACTIL WS: Dexibuprofen	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	400 mg if needed	Feb2016	Sep2018	
		07OCT2014	-	SERACTIL WS: Dexibuprofen	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	400 mg if needed	Feb2016	Sep2018	
		07OCT2014	-	SIRDALUD 4 mg (Tizanidin-Hydroc hlorid)	TIZANIDINE HYDROCHLORIDE	MUSCLE RELAXANTS	Pain-study-rela ted (AE no. 04)	0/0/0/1	03Jan2018	Mar2019	AE-4
		07OCT2014	-	PERFALGAN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1000 mg	07Oct2014	07Oct2014	
01/0126	ND basic	08OCT2014	08JAN2015	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	800-1200 mg	09Oct2014	06Nov2014	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0126	ND basic	08OCT2014	08JAN2015	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	800-1200 mg	09Oct2014	06Nov2014		
		08OCT2014	08JAN2015	Proxen (Naproxen)	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 07)	500 mg	01Mar2015	03Mar2015		AE-7
		08OCT2014	08JAN2015	Proxen (Naproxen)	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 07)	500 mg	01Mar2015	03Mar2015		AE-7
		08OCT2014	08JAN2015	Proxen (Naproxen)	NAPROXEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 07)	500 mg	01Mar2015	03Mar2015		AE-7
		08OCT2014	08JAN2015	Proxen (Naproxen)	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 07)	500 mg	01Mar2015	03Mar2015		AE-7
		08OCT2014	08JAN2015	Proxen (Naproxen)	NAPROXEN	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 07)	500 mg	01Mar2015	03Mar2015		AE-7
		08OCT2014	08JAN2015	Novalgine (Metamizole)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1000 mg	08Oct2014	09Oct2014		
		08OCT2014	08JAN2015	Novalgine (Metamizole)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 07)	150 mg	04Mar2015	24Mar2015		AE-7
		08OCT2014	08JAN2015	Dipidolor	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	7.5 mg	08Oct2014	10Oct2014		
		08OCT2014	08JAN2015	Seractil Forte	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	400 mg	08Jan2015	05Feb2015		
		08OCT2014	08JAN2015	Seractil Forte	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	400 mg	08Jan2015	05Feb2015		
		08OCT2014	08JAN2015	Seractil Forte	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 07)	400-1200 mg if needed	14Feb2015	May2019		AE-7

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0126	ND basic	08OCT2014	08JAN2015	Seractil Forte	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 07)	400-1200 mg if needed	14Feb2015	May2019		AE-7
		08OCT2014	08JAN2015	Dipidolor	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted (AE no. 07)	7.5-15 mg	05Mar2015	10Mar2015		AE-7
		08OCT2014	08JAN2015	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	400 mg if needed	14Feb2015	May2019		
		08OCT2014	08JAN2015	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	400 mg if needed	14Feb2015	May2019		
		08OCT2014	08JAN2015	Mexalen	PARACETAMOL	ANALGESICS	Pain-study-rela ted	2000 mg	10Oct2014	05Nov2014		
		08OCT2014	08JAN2015	Sirdalud	TIZANIDINE HYDROCHLORIDE	MUSCLE RELAXANTS	Pain-study-rela ted (AE no. 07)	4 mg	23Feb2015	03Mar2015		AE-7
01/0127	ND plus	20OCT2014	09JAN2015	IBUPROFEN	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1200 mg	02Oct2014	24Oct2014		
		20OCT2014	09JAN2015	IBUPROFEN	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1200 mg	02Oct2014	24Oct2014		
		20OCT2014	09JAN2015	IBUPROFEN	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1200 mg	02Oct2014	24Oct2014		
		20OCT2014	09JAN2015	IBUPROFEN	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1200 mg	02Oct2014	24Oct2014		
		20OCT2014	09JAN2015	IBUPROFEN	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1200 mg	02Oct2014	24Oct2014		
		20OCT2014	09JAN2015	Toxicodendron quercifolium c30	TOXICODENDRON PUBESCENS	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	Pain-study-rela ted	12 p/pice	29Dec2016	07Jan2017		
		20OCT2014	09JAN2015	Toxicodendron quercifolium c30	TOXICODENDRON PUBESCENS	HOMEOPATHIC PREPARATION	Pain-study-rela ted	12 p/pice	29Dec2016	07Jan2017		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0127	ND plus	20OCT2014	09JAN2015	SIRDALUD	TIZANIDINE HYDROCHLORIDE	MUSCLE RELAXANTS	Pain-study-rela ted	4 mg	02Oct2014	29Nov2014		
		20OCT2014	09JAN2015	Toxicodendron quercifolium c30	TOXICODENDRON PUBESCENS	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	Pain-study-rela ted	5 p/pice	10Jan2017	20Jan2017		
		20OCT2014	09JAN2015	Toxicodendron quercifolium c30	TOXICODENDRON PUBESCENS	HOMEOPATHIC PREPARATION	Pain-study-rela ted	5 p/pice	10Jan2017	20Jan2017		
		20OCT2014	09JAN2015	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 04)	8 mg	15Feb2018	21Feb2018		AE-4
		20OCT2014	09JAN2015	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 04)	8 mg	15Feb2018	21Feb2018		AE-4
		20OCT2014	09JAN2015	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	Pain-study-rela ted (AE no. 04)	8 mg	15Feb2018	21Feb2018		AE-4
		20OCT2014	09JAN2015	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	Pain-study-rela ted (AE no. 04)	8 mg	15Feb2018	21Feb2018		AE-4
		20OCT2014	09JAN2015	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-study-rela ted (AE no. 04)	8 mg	15Feb2018	21Feb2018		AE-4
		20OCT2014	09JAN2015	Fortecortin	DEXAMETHASONE	OTOLOGICALS	Pain-study-rela ted (AE no. 04)	8 mg	15Feb2018	21Feb2018		AE-4
		20OCT2014	09JAN2015	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Pain-study-rela ted (AE no. 04)	8 mg	15Feb2018	21Feb2018		AE-4
		20OCT2014	09JAN2015	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 04)	8 mg	15Feb2018	21Feb2018		AE-4
		20OCT2014	09JAN2015	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Pain-study-rela ted (AE no. 04)	8 mg	15Feb2018	21Feb2018		AE-4
		20OCT2014	09JAN2015	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 04)	8 mg	15Feb2018	21Feb2018		AE-4
		20OCT2014	09JAN2015	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-study-rela ted (AE no. 04)	8 mg	15Feb2018	21Feb2018		AE-4

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0127	ND plus	20OCT2014	09JAN2015	SERACTIL FORTE	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	800 mg	09Jan2015	10Jan2015	
		20OCT2014	09JAN2015	SERACTIL FORTE	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	800 mg	09Jan2015	10Jan2015	
		20OCT2014	09JAN2015	Toxicodendron quercifolium c30	TOXICODENDRON PUBESCENS	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	Pain-study-rela ted	17 p/pice	21Oct2016	31Oct2016	
		20OCT2014	09JAN2015	Toxicodendron quercifolium c30	TOXICODENDRON PUBESCENS	HOMEOPATHIC PREPARATION	Pain-study-rela ted	17 p/pice	21Oct2016	31Oct2016	
01/0128	ND plus	21OCT2014	13JAN2015	PROXEN (NAPROBENE)	NAPROXEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	500 mg	06Oct2014	01Nov2014	
		21OCT2014	13JAN2015	PROXEN (NAPROBENE)	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	500 mg	06Oct2014	01Nov2014	
		21OCT2014	13JAN2015	PROXEN (NAPROBENE)	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	500 mg	06Oct2014	01Nov2014	
		21OCT2014	13JAN2015	PROXEN (NAPROBENE)	NAPROXEN	OPHTHALMOLOGICA LS	Pain-study-rela ted	500 mg	06Oct2014	01Nov2014	
		21OCT2014	13JAN2015	PROXEN (NAPROBENE)	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	500 mg	06Oct2014	01Nov2014	
		21OCT2014	13JAN2015	SERACTIL FORTE	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	800 mg	14Jan2015	20Jan2015	
		21OCT2014	13JAN2015	SERACTIL FORTE	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	800 mg	14Jan2015	20Jan2015	
		21OCT2014	13JAN2015	DIPIDOLOR	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	15 mg	13Jan2015	13Jan2015	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0128	ND plus	21OCT2014	13JAN2015	PERFALGAN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1000 mg	23Oct2014	23Oct2014		
		21OCT2014	13JAN2015	DIPIDOLOR	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	7.5 mg	20Oct2014	21Oct2014		
		21OCT2014	13JAN2015	MEXALEN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1500 mg	14Jan2015	20Jun2015		
01/0129	SC	29OCT2014	-	PERFALGAN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1000 mg	29Oct2014	01Nov2014		
		29OCT2014	-	DIPIDOLOR	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	7.5 mg	29Oct2014	29Oct2014		
		29OCT2014	-	NOVALGIN (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1500 mg	01Nov2014	15Nov2014		
		29OCT2014	-	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	400 mg	14Oct2014	15Nov2014		
		29OCT2014	-	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	400 mg	14Oct2014	15Nov2014		
01/0130	ND basic	20NOV2014	03FEB2015	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	800 mg	25Sep2014	27Nov2014		
		20NOV2014	03FEB2015	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	800 mg	25Sep2014	27Nov2014		
		20NOV2014	03FEB2015	PERFALGAN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1000 mg	03Feb2015	03Feb2015		
		20NOV2014	03FEB2015	SIRDALUD	TIZANIDINE HYDROCHLORIDE	MUSCLE RELAXANTS	Pain-study-rela ted	4 mg	19Nov2014	27Nov2014		
01/0131	ND plus	01DEC2014	19FEB2015	Hydal	HYDROMORPHONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	4 mg	24Nov2014	11Dec2014		
		01DEC2014	19FEB2015	Perfalgan	PARACETAMOL	ANALGESICS	Pain-study-rela ted	3000 mg	24Nov2014	05Dec2014		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0131	ND plus	01DEC2014	19FEB2015	Dipidolor	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	7.5 mg if needed	24Nov2014	02Dec2014		
01/0132	SC	02DEC2014	-	MEXALEN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	500 mg	01Dec2014	02Dec2014		
		02DEC2014	-	DIPIDOLOR	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	7.5 mg	02Dec2014	02Dec2014		
		02DEC2014	-	DICLOFENAC	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	150 mg	02Dec2014	05Dec2014		
		02DEC2014	-	DICLOFENAC	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	150 mg	02Dec2014	05Dec2014		
		02DEC2014	-	DICLOFENAC	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted	150 mg	02Dec2014	05Dec2014		
		02DEC2014	-	DICLOFENAC	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	150 mg	02Dec2014	05Dec2014		
		02DEC2014	-	DICLOFENAC	DICLOFENAC	THROAT PREPARATIONS	Pain-study-rela ted	150 mg	02Dec2014	05Dec2014		
		02DEC2014	-	DICLOFENAC	DICLOFENAC	OPHTHALMOLOGICA LS	Pain-study-rela ted	150 mg	02Dec2014	05Dec2014		
		02DEC2014	-	METAMIZOLE	METAMIZOLE	ANALGESICS	Pain-study-rela ted	1500 mg	03Dec2014	05Dec2014		
		02DEC2014	-	PERFALGAN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1000 mg	02Dec2014	02Dec2014		
01/0133	ND plus	16DEC2014	-	NOVALGIN (METAMIZOLE)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	2000 mg	27Oct2014		Yes	
		16DEC2014	-	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	800 mg	17Dec2014		Yes	
		16DEC2014	-	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	800 mg	17Dec2014		Yes	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0133	ND plus	16DEC2014	-	DIPIDOLOR	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	7.5 - 1.5 mg	16Dec2014	19Dec2014		
01/0134	ND basic	17DEC2014	-	SERACTIL FORTE	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	800 mg	16Dec2014		Yes	
		17DEC2014	-	SERACTIL FORTE	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	800 mg	16Dec2014		Yes	
		17DEC2014	-	DIPIDOLOR	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	7.5 mg	17Dec2014	17Dec2014		
01/0135	ND plus	15JAN2015	08APR2015	DIPIDOLOR	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	7.5 mg if needed	15Jan2015	16Jan2015		
		15JAN2015	08APR2015	SERACTIL FORTE	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	400 mg if needed	12Nov2014	Jul2017		
		15JAN2015	08APR2015	SERACTIL FORTE	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	400 mg if needed	12Nov2014	Jul2017		
		15JAN2015	08APR2015	PERFALGAN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1000 mg	17Jan2015	18Jan2015		
01/0136	ND basic	23FEB2015	02JUN2015	PROXEN (Naproxen)	NAPROXEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1500 mg	01Dec2014	18Feb2015		
		23FEB2015	02JUN2015	PROXEN (Naproxen)	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1500 mg	01Dec2014	18Feb2015		
		23FEB2015	02JUN2015	PROXEN (Naproxen)	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1500 mg	01Dec2014	18Feb2015		
		23FEB2015	02JUN2015	PROXEN (Naproxen)	NAPROXEN	OPHTHALMOLOGICA LS	Pain-study-rela ted	1500 mg	01Dec2014	18Feb2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0136	ND basic	23FEB2015	02JUN2015	PROXEN (Naproxen)	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	1500 mg	01Dec2014	18Feb2015		
		23FEB2015	02JUN2015	DIPIDOLOR	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	7.5 mg	23Feb2015	23Feb2015		
		23FEB2015	02JUN2015	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 03)	400 mg if needed	10Aug2015	May2019		AE-3
		23FEB2015	02JUN2015	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 03)	400 mg if needed	10Aug2015	May2019		AE-3
		23FEB2015	02JUN2015	Bucain 0.25% Infiltration	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 03)	1 ml	10Nov2015	10Nov2015		AE-3
		23FEB2015	02JUN2015	Bucain 0.25% Infiltration	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain-study-rela ted (AE no. 03)	1 ml	10Nov2015	10Nov2015		AE-3
		23FEB2015	02JUN2015	NEURONTIN	GABAPENTIN	ANALGESICS	Pain-study-rela ted (AE no. 03)	900 mg	24Nov2015		Yes	AE-3
		23FEB2015	02JUN2015	NEURONTIN	GABAPENTIN	ANTIEPILEPTICS	Pain-study-rela ted (AE no. 03)	900 mg	24Nov2015		Yes	AE-3
		23FEB2015	02JUN2015	NEURONTIN	GABAPENTIN	OTHER NERVOUS SYSTEM DRUGS	Pain-study-rela ted (AE no. 03)	900 mg	24Nov2015		Yes	AE-3
		23FEB2015	02JUN2015	Volon A Infiltration (TRIAMCINOLON ACETONID)	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-study-rela ted (AE no. 03)	40 mg	10Nov2015	10Nov2015		AE-3
		23FEB2015	02JUN2015	Volon A Infiltration (TRIAMCINOLON ACETONID)	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 03)	40 mg	10Nov2015	10Nov2015		AE-3
		23FEB2015	02JUN2015	Volon A Infiltration (TRIAMCINOLON ACETONID)	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 03)	40 mg	10Nov2015	10Nov2015		AE-3
		23FEB2015	02JUN2015	Volon A Infiltration (TRIAMCINOLON ACETONID)	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-study-rela ted (AE no. 03)	40 mg	10Nov2015	10Nov2015		AE-3

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0136	ND basic	23FEB2015	02JUN2015	Volon A Infiltration (TRIAMCINOLON ACETONID)	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Pain-study-rela ted (AE no. 03)	40 mg	10Nov2015	10Nov2015		AE-3
		23FEB2015	02JUN2015	Volon A Infiltration (TRIAMCINOLON ACETONID)	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Pain-study-rela ted (AE no. 03)	40 mg	10Nov2015	10Nov2015		AE-3
		23FEB2015	02JUN2015	Volon A Infiltration (TRIAMCINOLON ACETONID)	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 03)	40 mg	10Nov2015	10Nov2015		AE-3
		23FEB2015	02JUN2015	SERACTIL forte	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	800 mg if needed	18Feb2015	May2019		
		23FEB2015	02JUN2015	SERACTIL forte	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	800 mg if needed	18Feb2015	May2019		
		23FEB2015	02JUN2015	BUCAIN 0.5% INFILTRATION	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 03)	1 ml	23Sep2015	23Sep2015		AE-3
		23FEB2015	02JUN2015	BUCAIN 0.5% INFILTRATION	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain-study-rela ted (AE no. 03)	1 ml	23Sep2015	23Sep2015		AE-3
		23FEB2015	02JUN2015	DEXABENE INFILTRATION	DEXAMETHASONE SODIUM PHOSPHATE	ANTI-ACNE PREPARATIONS	Pain-study-rela ted (AE no. 03)	4 mg	23Sep2015	23Sep2015		AE-3
		23FEB2015	02JUN2015	DEXABENE INFILTRATION	DEXAMETHASONE SODIUM PHOSPHATE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 03)	4 mg	23Sep2015	23Sep2015		AE-3
		23FEB2015	02JUN2015	DEXABENE INFILTRATION	DEXAMETHASONE SODIUM PHOSPHATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-study-rela ted (AE no. 03)	4 mg	23Sep2015	23Sep2015		AE-3
		23FEB2015	02JUN2015	DEXABENE INFILTRATION	DEXAMETHASONE SODIUM PHOSPHATE	OTOLOGICALS	Pain-study-rela ted (AE no. 03)	4 mg	23Sep2015	23Sep2015		AE-3

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing? MH/AE	Assoc iated with MH/AE
01/0136	ND basic	23FEB2015	02JUN2015	DEXABENE INFILTRATION	DEXAMETHASONE SODIUM PHOSPHATE	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 03)	4 mg	23Sep2015	23Sep2015		AE-3
		23FEB2015	02JUN2015	DEXABENE INFILTRATION	DEXAMETHASONE SODIUM PHOSPHATE	NASAL PREPARATIONS	Pain-study-rela ted (AE no. 03)	4 mg	23Sep2015	23Sep2015		AE-3
		23FEB2015	02JUN2015	DEXABENE INFILTRATION	DEXAMETHASONE SODIUM PHOSPHATE	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 03)	4 mg	23Sep2015	23Sep2015		AE-3
		23FEB2015	02JUN2015	DEXABENE INFILTRATION	DEXAMETHASONE SODIUM PHOSPHATE	VASOPROTECTIVES	Pain-study-rela ted (AE no. 03)	4 mg	23Sep2015	23Sep2015		AE-3
		23FEB2015	02JUN2015	DEXABENE INFILTRATION	DEXAMETHASONE SODIUM PHOSPHATE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 03)	4 mg	23Sep2015	23Sep2015		AE-3
01/0137	ND plus	26FEB2015	02JUN2015	SERACTIL forte	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1200 mg	27Feb2015	18Mar2015		
		26FEB2015	02JUN2015	SERACTIL forte	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1200 mg	27Feb2015	18Mar2015		
01/0138	SC	09MAR2015	-	SERACTIL forte	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	800-1200 mg	08Mar2015	14Mar2015		
		09MAR2015	-	SERACTIL forte	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	800-1200 mg	08Mar2015	14Mar2015		
		09MAR2015	-	NOVALGIN (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1500 mg	09Mar2015	13Mar2015		
01/0139	ND plus	10MAR2015	03JUN2015	DIPIDOLOR	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	7.5-15 mg	11Mar2015	11Mar2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0139	ND plus	10MAR2015	03JUN2015	NAPROBENE	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 02)	1000 mg	11Dec2016	Feb2017		AE-2
		10MAR2015	03JUN2015	NAPROBENE	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 02)	1000 mg	11Dec2016	Feb2017		AE-2
		10MAR2015	03JUN2015	NAPROBENE	NAPROXEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 02)	1000 mg	11Dec2016	Feb2017		AE-2
		10MAR2015	03JUN2015	NAPROBENE	NAPROXEN	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 02)	1000 mg	11Dec2016	Feb2017		AE-2
		10MAR2015	03JUN2015	NAPROBENE	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 02)	1000 mg	11Dec2016	Feb2017		AE-2
		10MAR2015	03JUN2015	SIRDALUD	TIZANIDINE HYDROCHLORIDE	MUSCLE RELAXANTS	Pain-study-rela ted	6 mg	06Mar2015	03Apr2015		
		10MAR2015	03JUN2015	NAPROBENE	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1000 mg	06Mar2015	29Mar2015		
		10MAR2015	03JUN2015	NAPROBENE	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1000 mg	06Mar2015	29Mar2015		
		10MAR2015	03JUN2015	NAPROBENE	NAPROXEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1000 mg	06Mar2015	29Mar2015		
		10MAR2015	03JUN2015	NAPROBENE	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	1000 mg	06Mar2015	29Mar2015		
		10MAR2015	03JUN2015	NAPROBENE	NAPROXEN	OPHTHALMOLOGICA LS	Pain-study-rela ted	1000 mg	06Mar2015	29Mar2015		
		10MAR2015	03JUN2015	PERFALGAN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	3000 mg	06Mar2015	12Mar2015		
01/0140	ND basic	12MAY2015	11AUG2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1200 mg	15Mar2015	03Jun2015		
		12MAY2015	11AUG2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1200 mg	15Mar2015	03Jun2015		
		12MAY2015	11AUG2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1200 mg	15Mar2015	03Jun2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
01/0140	ND basic	12MAY2015	11AUG2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1200 mg	15Mar2015	03Jun2015	
		12MAY2015	11AUG2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1200 mg	15Mar2015	03Jun2015	
		12MAY2015	11AUG2015	Tramabene	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	100 mg if needed	2014	2017	
		12MAY2015	11AUG2015	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	800 g	11May2015	11May2015	
		12MAY2015	11AUG2015	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	800 g	11May2015	11May2015	
		12MAY2015	11AUG2015	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	800 g	13May2015	18May2015	
		12MAY2015	11AUG2015	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	800 g	13May2015	18May2015	
01/0141	SC	27MAY2015	-	NEODOLPASSE	NEODOLPASSE	MUSCLE RELAXANTS	Pain-study-rela ted	250 ml	05May2015	25May2015	
		27MAY2015	-	VENDAL	MORPHINE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	10 mg	27May2015	27May2015	
		27MAY2015	-	PROXEN (Naproxen)	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1500 mg	01May2015	03Jun2015	
		27MAY2015	-	PROXEN (Naproxen)	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1500 mg	01May2015	03Jun2015	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0141	SC	27MAY2015	-	PROXEN (Naproxen)	NAPROXEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1500 mg	01May2015	03Jun2015		
		27MAY2015	-	PROXEN (Naproxen)	NAPROXEN	OPHTHALMOLOGICA LS	Pain-study-rela ted	1500 mg	01May2015	03Jun2015		
		27MAY2015	-	PROXEN (Naproxen)	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	1500 mg	01May2015	03Jun2015		
		27MAY2015	-	METAMIZOLE	METAMIZOLE	ANALGESICS	Pain-study-rela ted	500 mg	26May2015	26May2015		
01/0142	ND plus	27MAY2015	25AUG2015	DIPIDOLOR	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	7.5 mg	28May2015	28May2015		
		27MAY2015	25AUG2015	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1200 mg	26May2015	04Jun2015		
		27MAY2015	25AUG2015	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1200 mg	26May2015	04Jun2015		
		27MAY2015	25AUG2015	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1200 mg	25Aug2015	26Aug2015		
		27MAY2015	25AUG2015	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1200 mg	25Aug2015	26Aug2015		
		27MAY2015	25AUG2015	METAMIZOLE	METAMIZOLE	ANALGESICS	Pain-study-rela ted	1500 mg	28May2015	04Jun2015		
		27MAY2015	25AUG2015	PERFALGAN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1000 mg	27May2015	27May2015		
01/0143	ND plus	17JUN2015	22SEP2015	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	800 mg	16Jun2015	27Jun2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0143	ND plus	17JUN2015	22SEP2015	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	800 mg	16Jun2015	27Jun2015		
		17JUN2015	22SEP2015	PERFALGAN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1000 mg	22Sep2015	23Sep2015		
01/0144	ND basic	24JUN2015	22SEP2015	PARKEMED	MEFENAMIC ACID	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1500 mg	22Jun2015	30Jun2015		
		24JUN2015	22SEP2015	NOVALGIN (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1500 mg	25Jun2015	26Jun2015		
01/0145	ND plus	16JUL2015	07OCT2015	PERFALGAN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1000 mg	16Jul2015	16Jul2015		
		16JUL2015	07OCT2015	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	800-1200 mg	16Jul2015	25Jul2015		
		16JUL2015	07OCT2015	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	800-1200 mg	16Jul2015	25Jul2015		
		16JUL2015	07OCT2015	NOVALGIN (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1500 mg	17Jul2015	20Jul2015		
01/0146	SC	16JUL2015	-	NAPROXEN	NAPROXEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 01) needed	500 mg if	01Mar2016		Yes	AE-1
		16JUL2015	-	NAPROXEN	NAPROXEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 01) needed	500 mg if	01Mar2016		Yes	AE-1
		16JUL2015	-	NAPROXEN	NAPROXEN	OTHER	Pain-study-rela ted (AE no. 01) needed	500 mg if	01Mar2016		Yes	AE-1
		16JUL2015	-	NAPROXEN	NAPROXEN	GYNECOLOGICALS OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 01) needed	500 mg if	01Mar2016		Yes	AE-1

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0146	SC	16JUL2015	-	NAPROXEN	NAPROXEN	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 01)	500 mg if needed	01Mar2016		Yes	AE-1
		16JUL2015	-	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1200 mg	15Jul2015	01Aug2015		
		16JUL2015	-	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1200 mg	15Jul2015	01Aug2015		
		16JUL2015	-	PERFALGAN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1000-3000 mg	16Jul2015	20Jul2015		
		16JUL2015	-	DIPIDOLOR	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	7.5 mg	16Jul2015	17Jul2015		
01/0147	ND plus	20AUG2015	18NOV2015	METAMIZOLE	METAMIZOLE	ANALGESICS	Pain-study-rela ted	1000 mg	17Aug2015	03Sep2015		
01/0148	ND plus	22OCT2015	12JAN2016	Novalgin (Metamizole)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1500 mg	12Jan2016	13Jan2016		
		22OCT2015	12JAN2016	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1200 mg	23Oct2015	02Nov2015		
		22OCT2015	12JAN2016	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1200 mg	23Oct2015	02Nov2015		
		22OCT2015	12JAN2016	Novalgin (Metamizole)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	500-1500 mg	21Oct2015	26Oct2015		
01/0149	ND plus	03DEC2015	01MAR2016	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1200 mg	01Dec2015	09Dec2015		
		03DEC2015	01MAR2016	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1200 mg	01Dec2015	09Dec2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
01/0150		03FEB2016	-	PARKEMED	MEFENAMIC ACID	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	500 mg if needed	01Sep2015		Yes	
		03FEB2016	-	MEXALEN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	500 mg if needed	01Sep2015		Yes	
01/0151	ND basic	03MAR2016	07JUN2016	PERFALGAN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	2000 mg	29Feb2016	06Mar2016		
		03MAR2016	07JUN2016	PERFALGAN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1000 mg	07Jun2016	07Jun2016		
		03MAR2016	07JUN2016	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	800 mg	18Jan2016	06Mar2016		
		03MAR2016	07JUN2016	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	800 mg	18Jan2016	06Mar2016		
		03MAR2016	07JUN2016	DIPIDOLOR	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	15 mg	29Feb2016	03Mar2016		
		03MAR2016	07JUN2016	MEXALEN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	2000 mg	18Jan2016	29Feb2016		
		03MAR2016	07JUN2016	NOVALGIN (METAMIZOLE)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1000 mg	29Feb2016	06Mar2016		
01/0152	SC	03MAR2016	-	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1200 mg	04Mar2016	14Mar2016		
		03MAR2016	-	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1200 mg	04Mar2016	14Mar2016		
		03MAR2016	-	Seractil	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 04) as needed	800 mg/400 mg	Feb2018	Mar2018		AE-4

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing? MH/AE	Assoc iated with MH/AE
01/0152	SC	03MAR2016	-	Seractil	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 04)	800 mg/400 mg as needed	Feb2018	Mar2018		AE-4
		03MAR2016	-	NOVALGIN (METAMIZOLE)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1500 mg	04Mar2016	14Mar2016		
		03MAR2016	-	PARKEMED	MEFENAMIC ACID	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	400 mg if needed	Nov2015	14Mar2016		
		03MAR2016	-	DIPIDOLOR	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	7.5 mg	03Mar2016	03Mar2016		
01/0153	ND basic	21MAR2016	07JUN2016	NOVALGIN (METAMIZOLE)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	300 mg	08Mar2016	28Mar2016		
		21MAR2016	07JUN2016	SERACTIL	DEXIBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1200 mg	22Mar2016	28Mar2016		
		21MAR2016	07JUN2016	SERACTIL	DEXIBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1200 mg	22Mar2016	28Mar2016		
		21MAR2016	07JUN2016	PERFALGAN	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1000 mg	21Mar2016	21Mar2016		
		21MAR2016	07JUN2016	DIPIDOLOR	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	7.5 mg	22Mar2016	22Mar2016		
		21MAR2016	07JUN2016	VENDAL	MORPHINE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	5 mg	07Jun2016	07Jun2016		
02/0201	ND plus	13FEB2013	07MAY2013	Ibuprofen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain	1800 MG	12Feb2013	15Feb2013		
		13FEB2013	07MAY2013	Ibuprofen 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain	1800 MG	12Feb2013	15Feb2013		
		13FEB2013	07MAY2013	Ibuprofen 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1800 MG	12Feb2013	15Feb2013		
		13FEB2013	07MAY2013	Ibuprofen 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain	1800 MG	12Feb2013	15Feb2013		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0201	ND plus	13FEB2013	07MAY2013	Ibuprofen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1800 MG	12Feb2013	15Feb2013	
		13FEB2013	07MAY2013	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain	4500 MG	12Feb2013	19Feb2013	
		13FEB2013	07MAY2013	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1200 MG	15Feb2013	Feb2013	
		13FEB2013	07MAY2013	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain	1200 MG	15Feb2013	Feb2013	
		13FEB2013	07MAY2013	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1200 MG	15Feb2013	Feb2013	
		13FEB2013	07MAY2013	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain	1200 MG	15Feb2013	Feb2013	
		13FEB2013	07MAY2013	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain	1200 MG	15Feb2013	Feb2013	
		13FEB2013	07MAY2013	Oxygesic akut 5 mg	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain	5 MG	12Feb2013	20Feb2013	
		13FEB2013	07MAY2013	Novalgin 500 mg/ml (Metamizol-Natriu m)	METAMIZOLE SODIUM	ANALGESICS	Pain	30 DROPS	12Feb2013	20Feb2013	
		13FEB2013	07MAY2013	Ibuprofen 600	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	600 MG	07May2013	09May2013	
		13FEB2013	07MAY2013	Ibuprofen 600	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	600 MG	07May2013	09May2013	
		13FEB2013	07MAY2013	Ibuprofen 600	IBUPROFEN	OTHER GYNECOLOGICALS	Pain	600 MG	07May2013	09May2013	
		13FEB2013	07MAY2013	Ibuprofen 600	IBUPROFEN	THROAT PREPARATIONS	Pain	600 MG	07May2013	09May2013	
		13FEB2013	07MAY2013	Ibuprofen 600	IBUPROFEN	CARDIAC THERAPY	Pain	600 MG	07May2013	09May2013	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0201	ND plus	13FEB2013	07MAY2013	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain	2250 MG	19Feb2013	Feb2013	
02/0202	ND basic	20MAR2013	-	Ibuprofen 600	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	3 X 1=800 MG	14Mar2013	Apr2013	
		20MAR2013	-	Ibuprofen 600	IBUPROFEN	OTHER GYNECOLOGICALS	Pain	3 X 1=800 MG	14Mar2013	Apr2013	
		20MAR2013	-	Ibuprofen 600	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	3 X 1=800 MG	14Mar2013	Apr2013	
		20MAR2013	-	Ibuprofen 600	IBUPROFEN	THROAT PREPARATIONS	Pain	3 X 1=800 MG	14Mar2013	Apr2013	
		20MAR2013	-	Ibuprofen 600	IBUPROFEN	CARDIAC THERAPY	Pain	3 X 1=800 MG	14Mar2013	Apr2013	
		20MAR2013	-	Ortofon 750	METHOCARBAMOL	MUSCLE RELAXANTS	Pain	3 X 2=4500 MG	14Mar2013	26Mar2013	
		20MAR2013	-	Novalgin 500 mg/ml (Metamizol-Natriu m)	METAMIZOLE SODIUM	ANALGESICS	Pain	1 X 30-120 DROPS	14Mar2013	27Mar2013	
		20MAR2013	-	Oxygesic-acut Kps 5 mg	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain	1 X 1=5 MG	14Mar2013	27Mar2013	
		20MAR2013	-	Paracetamol 1000 mg/100 ml	PARACETAMOL	ANALGESICS	Pain	3 X 1 3000 MG	18Mar2013	19Mar2013	
		20MAR2013	-	Oxycodon 20 mg	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain	2 X 2 40 MG	18Mar2013	Apr2013	
		20MAR2013	-	Ortoton 750 mg	METHOCARBAMOL	MUSCLE RELAXANTS	Pain	3 X 1 2250 MG	26Mar2013	Apr2013	
02/0203	ND basic	28MAR2013	26JUN2013	Katadolon / Flurpiritin	FLUPIRTINE MALEATE	ANALGESICS	Pain	100 MG	24Feb2014	26Feb2014	
		28MAR2013	26JUN2013	Novalgin / Metamizol	METAMIZOLE SODIUM	ANALGESICS	Pain	4x40 1000 MG/DAILY	28Feb2014	04Mar2014	
		28MAR2013	26JUN2013	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1.8 G	27Mar2013	03Apr2013	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0203	ND basic	28MAR2013	26JUN2013	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain	1.8 G	27Mar2013	03Apr2013	
		28MAR2013	26JUN2013	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1.8 G	27Mar2013	03Apr2013	
		28MAR2013	26JUN2013	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain	1.8 G	27Mar2013	03Apr2013	
		28MAR2013	26JUN2013	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain	1.8 G	27Mar2013	03Apr2013	
		28MAR2013	26JUN2013	Arcoxia 90	ETORICOXIB	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	UNK	2016	26Jun2018	
		28MAR2013	26JUN2013	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain	4500 MG	27Mar2013	03Apr2013	
		28MAR2013	26JUN2013	Novalgin 500 mg/ml (Metamizol-Natriu m)	METAMIZOLE SODIUM	ANALGESICS	Pain	AS NEEDED	25Jun2013	28Jun2013	
		28MAR2013	26JUN2013	Oxygesic	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain	5 MG	25Jun2013	28Jun2013	
02/0205	ND basic	18APR2013	31JUL2013	Oxygesic-akut Kps 5 mg	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain	5 MG	16Apr2013	25Apr2013	
		18APR2013	31JUL2013	Ortoton-Tbl 750 mg	METHOCARBAMOL	MUSCLE RELAXANTS	Pain	4500 MG	16Apr2013	Apr2013	
		18APR2013	31JUL2013	Ibuprofen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1800 MG	16Apr2013	Apr2013	
		18APR2013	31JUL2013	Ibuprofen 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1800 MG	16Apr2013	Apr2013	
		18APR2013	31JUL2013	Ibuprofen 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain	1800 MG	16Apr2013	Apr2013	
		18APR2013	31JUL2013	Ibuprofen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain	1800 MG	16Apr2013	Apr2013	
		18APR2013	31JUL2013	Ibuprofen 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain	1800 MG	16Apr2013	Apr2013	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0205	ND basic	18APR2013	31JUL2013	Novalgin Trpf (500 mg/ml, Metamizol-Natrium)	METAMIZOLE SODIUM	ANALGESICS	Pain	30-120 DROPS	16Apr2013	25Apr2013		
		18APR2013	31JUL2013	Novalgin (500 mg/ml, Metamizol-Natrium)	METAMIZOLE SODIUM	ANALGESICS	Pain	30-120 DROPS	30Jul2013	02Aug2013		
		18APR2013	31JUL2013	Oxygesic	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain	5 MG	30Jul2013	02Aug2013		
02/0208	ND plus	12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain	1800 MG	13Sep2013	03Oct2013		
		12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain	1800 MG	13Sep2013	03Oct2013		
		12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1800 MG	13Sep2013	03Oct2013		
		12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain	1800 MG	13Sep2013	03Oct2013		
		12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1800 MG	13Sep2013	03Oct2013		
		12SEP2013	10DEC2013	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain	4500 MG	16Dec2013	20Dec2013		
		12SEP2013	10DEC2013	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain	4500 MG	02Apr2014	Mar2014		
		12SEP2013	10DEC2013	Oxygesic (Oxycodon)	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela	5 mg as needed	21Sep2015	28Sep2015		AE-4
		12SEP2013	10DEC2013	Valoron N retard (Naloxon+Tilidin)	VALORON N	ANALGESICS	ted (AE no. 04) Pain	40 MG	11Sep2013	03Oct2013		
		12SEP2013	10DEC2013	Oxygesic akut	/00628301/ OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain	5 MG	16Dec2013	19Dec2013		
		12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1800 MG	02Apr2014	Mar2014		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0208	ND plus	12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1800 MG	02Apr2014	Mar2014	
		12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain	1800 MG	02Apr2014	Mar2014	
		12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain	1800 MG	02Apr2014	Mar2014	
		12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain	1800 MG	02Apr2014	Mar2014	
		12SEP2013	10DEC2013	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain	4500 MG	13Sep2013	03Oct2013	
		12SEP2013	10DEC2013	Tilidin	VALORON N	ANALGESICS	Pain	50 MG IF NEEDED	19Dec2013	19Dec2013	
		12SEP2013	10DEC2013	Oxygesic akut (Oxycodon)	/00628301/ OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain	5 MG	01Apr2014	08Apr2014	
		12SEP2013	10DEC2013	Oxygesic - akut 5 mg	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain	5 MG	13Sep2013	20Sep2013	
		12SEP2013	10DEC2013	Novalgin Trpf (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain	30-120 TRPF	01Apr2014	08Apr2014	
		12SEP2013	10DEC2013	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain	4500 MG	09Dec2013	14Dec2013	
		12SEP2013	10DEC2013	Tilidin	VALORON N	ANALGESICS	Pain	20 TRPF.	Jul2014	2014	
		12SEP2013	10DEC2013	Ibuprofen	/00628301/ IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1800 MG	09Dec2013	14Dec2013	
		12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain	1800 MG	09Dec2013	14Dec2013	
		12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1800 MG	09Dec2013	14Dec2013	
		12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain	1800 MG	09Dec2013	14Dec2013	
		12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain	1800 MG	09Dec2013	14Dec2013	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0208	ND plus	12SEP2013	10DEC2013	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain	30-120 TRPF. 500 MG/ML	21Sep2015	28Sep2015	
		12SEP2013	10DEC2013	Oxygesic-akut Kps	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain	5 MG	09Dec2013	12Dec2013	
		12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	1800 MG	21Sep2015	Oct2015	
		12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain	1800 MG	21Sep2015	Oct2015	
		12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	1800 MG	21Sep2015	Oct2015	
		12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain	1800 MG	21Sep2015	Oct2015	
		12SEP2013	10DEC2013	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain	1800 MG	21Sep2015	Oct2015	
		12SEP2013	10DEC2013	Tilidin	VALORON N	ANALGESICS	Pain	50 MG X 2 100 MG	16Dec2013	19Dec2013	
		12SEP2013	10DEC2013	Ortototon	/00628301/ METHOCARBAMOL	MUSCLE RELAXANTS	Pain	4500 MG	21Sep2015	Oct2015	
		12SEP2013	10DEC2013	Ortototon	METHOCARBAMOL	MUSCLE RELAXANTS	Pain	4500 MG	21Sep2015	Oct2015	
02/0209	ND plus	23OCT2014	30JAN2015	Ortototon	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	4500 mg	18Sep2014	02Oct2014	
		23OCT2014	30JAN2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1800 mg	22Oct2014	Nov2014	
		23OCT2014	30JAN2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1800 mg	22Oct2014	Nov2014	
		23OCT2014	30JAN2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1800 mg	22Oct2014	Nov2014	
		23OCT2014	30JAN2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1800 mg	22Oct2014	Nov2014	
		23OCT2014	30JAN2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg	22Oct2014	Nov2014	
		23OCT2014	30JAN2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg	22Oct2014	Nov2014	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0209	ND plus	23OCT2014	30JAN2015	Novalgin - Trpf. 500 mg/ml	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	30-120 drops	29Jan2015	01Feb2015	
		23OCT2014	30JAN2015	Voltaren	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	as needed	18Sep2014	02Oct2014	
		23OCT2014	30JAN2015	Voltaren	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	as needed	18Sep2014	02Oct2014	
		23OCT2014	30JAN2015	Voltaren	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted	as needed	18Sep2014	02Oct2014	
		23OCT2014	30JAN2015	Voltaren	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	as needed	18Sep2014	02Oct2014	
		23OCT2014	30JAN2015	Voltaren	DICLOFENAC	THROAT PREPARATIONS	Pain-study-rela ted	as needed	18Sep2014	02Oct2014	
		23OCT2014	30JAN2015	Voltaren	DICLOFENAC	OPHTHALMOLOGICA LS	Pain-study-rela ted	as needed	18Sep2014	02Oct2014	
		23OCT2014	30JAN2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg	18Sep2014	02Oct2014	
		23OCT2014	30JAN2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1800 mg	18Sep2014	02Oct2014	
		23OCT2014	30JAN2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1800 mg	18Sep2014	02Oct2014	
		23OCT2014	30JAN2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1800 mg	18Sep2014	02Oct2014	
		23OCT2014	30JAN2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1800 mg	18Sep2014	02Oct2014	
		23OCT2014	30JAN2015	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	4500 mg	22Oct2014	Nov2014	
		23OCT2014	30JAN2015	Oxygesic akut Kps	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	5 mg	29Jan2015	01Feb2015	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0210		13NOV2014	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg	25Sep2014	12Nov2014		
		13NOV2014	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1800 mg	25Sep2014	12Nov2014		
		13NOV2014	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1800 mg	25Sep2014	12Nov2014		
		13NOV2014	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1800 mg	25Sep2014	12Nov2014		
		13NOV2014	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1800 mg	25Sep2014	12Nov2014		
02/0211	ND basic	11DEC2014	-	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	4500 mg	11Dec2014	18Dec2014		
		11DEC2014	-	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	500 mg/ml as needed	10Dec2014	18Dec2014		
		11DEC2014	-	Oxygesic (Oxycodon)	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	5 mg as needed	10Dec2014	18Dec2014		
		11DEC2014	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1800 mg	11Dec2014	27Dec2014		
		11DEC2014	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg	11Dec2014	27Dec2014		
		11DEC2014	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1800 mg	11Dec2014	27Dec2014		
		11DEC2014	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1800 mg	11Dec2014	27Dec2014		
		11DEC2014	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1800 mg	11Dec2014	27Dec2014		
02/0212	SC	16DEC2014	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1800 mg	Nov2014	16Dec2014		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0212	SC	16DEC2014	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg	Nov2014	16Dec2014		
		16DEC2014	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1800 mg	Nov2014	16Dec2014		
		16DEC2014	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1800 mg	Nov2014	16Dec2014		
		16DEC2014	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1800 mg	Nov2014	16Dec2014		
		16DEC2014	-	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	750 mg	15Dec2014	16Dec2014		
		16DEC2014	-	Voltaren	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 02)	2x1	19Apr2019		Yes	AE-2
		16DEC2014	-	Voltaren	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 02)	2x1	19Apr2019		Yes	AE-2
		16DEC2014	-	Voltaren	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 02)	2x1	19Apr2019		Yes	AE-2
		16DEC2014	-	Voltaren	DICLOFENAC	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 02)	2x1	19Apr2019		Yes	AE-2
		16DEC2014	-	Voltaren	DICLOFENAC	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 02)	2x1	19Apr2019		Yes	AE-2
		16DEC2014	-	Voltaren	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 02)	2x1	19Apr2019		Yes	AE-2
		16DEC2014	-	Oxygesic (Oxycodon)	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	as needed 5 mg	15Dec2014	21Dec2014		
		16DEC2014	-	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	4500 mg	15Dec2014	23Dec2014		
		16DEC2014	-	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	500 mg	16Dec2014	Mar2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0213	ND plus	18DEC2014	-	Tillidin	VALORON N	ANALGESICS	Pain-study-rela ted	100 mg	02Dec2014	17Dec2014		
		18DEC2014	-	Valoron N50	/00628301/ VALORON N	ANALGESICS	Pain-study-rela ted	50/4mg 2x1	17Dec2014	09Mar2015		
		18DEC2014	-	Novalgin (Metamizol) Tprf	/00628301/ METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	500 mg/ml as needed 30-120 drops	17Dec2014	UNK		
02/0214	ND plus	25FEB2015	28MAY2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1800 mg	24Feb2015	Mar2015		
		25FEB2015	28MAY2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1800 mg	24Feb2015	Mar2015		
		25FEB2015	28MAY2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1800 mg	24Feb2015	Mar2015		
		25FEB2015	28MAY2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg	24Feb2015	Mar2015		
		25FEB2015	28MAY2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1800 mg	24Feb2015	Mar2015		
		25FEB2015	28MAY2015	Volon A40	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Pain-study-rela ted (AE no. 02)	1 ml	15Oct2020	15Oct2020		AE-2
		25FEB2015	28MAY2015	Volon A40	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-study-rela ted (AE no. 02)	1 ml	15Oct2020	15Oct2020		AE-2
		25FEB2015	28MAY2015	Volon A40	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 02)	1 ml	15Oct2020	15Oct2020		AE-2
		25FEB2015	28MAY2015	Volon A40	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Pain-study-rela ted (AE no. 02)	1 ml	15Oct2020	15Oct2020		AE-2
		25FEB2015	28MAY2015	Volon A40	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 02)	1 ml	15Oct2020	15Oct2020		AE-2
		25FEB2015	28MAY2015	Volon A40	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-study-rela ted (AE no. 02)	1 ml	15Oct2020	15Oct2020		AE-2

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0214	ND plus	25FEB2015	28MAY2015	Volon A40	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 02)	1 ml	15Oct2020	15Oct2020		AE-2
		25FEB2015	28MAY2015	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	4500 mg	24Feb2015	Mar2015		
		25FEB2015	28MAY2015	Xylochin 2 %	LIDOCAINE	UROLOGICALS	Pain-study-rela ted (AE no. 02)	1 ml	15Oct2020	15Oct2020		AE-2
		25FEB2015	28MAY2015	Xylochin 2 %	LIDOCAINE	ANTIPRURITICS, INCL. ANTIHIISTAMINES, ANESTHETICS, ETC.	Pain-study-rela ted (AE no. 02)	1 ml	15Oct2020	15Oct2020		AE-2
		25FEB2015	28MAY2015	Xylochin 2 %	LIDOCAINE	ANESTHETICS	Pain-study-rela ted (AE no. 02)	1 ml	15Oct2020	15Oct2020		AE-2
		25FEB2015	28MAY2015	Xylochin 2 %	LIDOCAINE	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 02)	1 ml	15Oct2020	15Oct2020		AE-2
		25FEB2015	28MAY2015	Xylochin 2 %	LIDOCAINE	CARDIAC THERAPY	Pain-study-rela ted (AE no. 02)	1 ml	15Oct2020	15Oct2020		AE-2
		25FEB2015	28MAY2015	Xylochin 2 %	LIDOCAINE	VASOPROTECTIVES	Pain-study-rela ted (AE no. 02)	1 ml	15Oct2020	15Oct2020		AE-2
		25FEB2015	28MAY2015	Xylochin 2 %	LIDOCAINE	OTOLOGICALS	Pain-study-rela ted (AE no. 02)	1 ml	15Oct2020	15Oct2020		AE-2
		25FEB2015	28MAY2015	Xylochin 2 %	LIDOCAINE	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 02)	1 ml	15Oct2020	15Oct2020		AE-2
		25FEB2015	28MAY2015	Xylochin 2 %	LIDOCAINE	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 02)	1 ml	15Oct2020	15Oct2020		AE-2
		25FEB2015	28MAY2015	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	500 mg/ml 50-120 drops	24Feb2015	02Mar2015		
		25FEB2015	28MAY2015	Oxygesic akut	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	5 mg	24Feb2015	02Mar2015		
		25FEB2015	28MAY2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	800 mg as needed	May2015	29May2015		
		25FEB2015	28MAY2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	800 mg as needed	May2015	29May2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0214	ND plus	25FEB2015	28MAY2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	800 mg as needed	May2015	29May2015	
		25FEB2015	28MAY2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	800 mg as needed	May2015	29May2015	
		25FEB2015	28MAY2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	800 mg as needed	May2015	29May2015	
02/0215		-	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	3x1600 mg	04Mar2015	Mar2015	
		-	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	3x1600 mg	04Mar2015	Mar2015	
		-	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	3x1600 mg	04Mar2015	Mar2015	
		-	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	3x1600 mg	04Mar2015	Mar2015	
		-	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	3x1600 mg	04Mar2015	Mar2015	
		-	-	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	4500 g	04Mar2015	Mar2015	
02/0216	ND plus	28APR2015	23JUL2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	2400 mg	27Apr2015	05May2015	
		28APR2015	23JUL2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	2400 mg	27Apr2015	05May2015	
		28APR2015	23JUL2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	2400 mg	27Apr2015	05May2015	
		28APR2015	23JUL2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	2400 mg	27Apr2015	05May2015	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0216	ND plus	28APR2015	23JUL2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	2400 mg	27Apr2015	05May2015	
		28APR2015	23JUL2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1800 mg	05May2015	May2015	
		28APR2015	23JUL2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1800 mg	05May2015	May2015	
		28APR2015	23JUL2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1800 mg	05May2015	May2015	
		28APR2015	23JUL2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1800 mg	05May2015	May2015	
		28APR2015	23JUL2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg	05May2015	May2015	
		28APR2015	23JUL2015	Sympal	DEXKETOPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	50 mg	29Jul2015	29Jul2015	
		28APR2015	23JUL2015	Sympal	DEXKETOPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	50 mg	29Jul2015	29Jul2015	
		28APR2015	23JUL2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	600 mg as needed	Aug2015	29Mar2016	
		28APR2015	23JUL2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	600 mg as needed	Aug2015	29Mar2016	
		28APR2015	23JUL2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	600 mg as needed	Aug2015	29Mar2016	
		28APR2015	23JUL2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	600 mg as needed	Aug2015	29Mar2016	
		28APR2015	23JUL2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	600 mg as needed	Aug2015	29Mar2016	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0216	ND plus	28APR2015	23JUL2015	Sirdalud	TIZANIDINE HYDROCHLORIDE	MUSCLE RELAXANTS	Pain-study-rela ted	2 mg 1-1-1	29Jul2015	07Aug2015	
		28APR2015	23JUL2015	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	6000 mg	27Apr2015	May2015	
		28APR2015	23JUL2015	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	500 mg as needed	23Jul2015	24Jul2015	
		28APR2015	23JUL2015	Tilidin 50/4mg	VALORON N	ANALGESICS	Pain-study-rela ted	2x1 Tbl.	07Aug2015	21Aug2015	
		28APR2015	23JUL2015	Novalgin (Metamizol)	/00628301/ METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	30 drops, 500 mg	29Jul2015	07Aug2015	
		28APR2015	23JUL2015	Oxygesic (Oxycodon)	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	5 mg as needed	23Jul2015	24Jul2015	
02/0217	SC	28MAY2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1600 mg	May2015	26May2015	
		28MAY2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1600 mg	May2015	26May2015	
		28MAY2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1600 mg	May2015	26May2015	
		28MAY2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1600 mg	May2015	26May2015	
		28MAY2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1600 mg	May2015	26May2015	
		28MAY2015	-	Dipidolor	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	as needed 6 x 7.5 mg	26May2015	04Jun2015	
		28MAY2015	-	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	750	04Jun2015	07Jun2015	
		28MAY2015	-	Oxycodon 10	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	20 mg	26May2015	29May2015	
		28MAY2015	-	Novalgin drops (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	as needed max 120 drops	26May2015	04Jun2015	
		28MAY2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg	26May2015	04Jun2015	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0217	SC	28MAY2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1800 mg	26May2015	04Jun2015		
		28MAY2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1800 mg	26May2015	04Jun2015		
		28MAY2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1800 mg	26May2015	04Jun2015		
		28MAY2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1800 mg	26May2015	04Jun2015		
		28MAY2015	-	Paracetamol KJ	PARACETAMOL	ANALGESICS	Pain-study-rela ted	3 g	26May2015	29May2015		
		28MAY2015	-	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	4500 mg	26May2015	04Jun2015		
		28MAY2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	600 mg	04Jun2015	07Jun2015		
		28MAY2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	600 mg	04Jun2015	07Jun2015		
		28MAY2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	600 mg	04Jun2015	07Jun2015		
		28MAY2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	600 mg	04Jun2015	07Jun2015		
02/0218	ND basic	30JUN2015	-	Voltaren resinat	DICLOFENAC RESINATE	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	150 mg	Apr2015		Yes	
		30JUN2015	-	Voltaren resinat	DICLOFENAC RESINATE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	150 mg	Apr2015		Yes	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0218	ND basic	30JUN2015	-	Voltaren resinat	DICLOFENAC RESINATE	OPHTHALMOLOGICA LS	Pain-study-rela ted	150 mg	Apr2015		Yes	
		30JUN2015	-	Oxygesic	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	5-20 mg as needed	30Jun2015	04Jul2015		
		30JUN2015	-	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	4500 mg	Apr2015		Yes	
02/0219	ND basic	11JUN2015	25SEP2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1800 mg	19May2015	12Jul2015		
		11JUN2015	25SEP2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg	19May2015	12Jul2015		
		11JUN2015	25SEP2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1800 mg	19May2015	12Jul2015		
		11JUN2015	25SEP2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1800 mg	19May2015	12Jul2015		
		11JUN2015	25SEP2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1800 mg	19May2015	12Jul2015		
		11JUN2015	25SEP2015	Novalgine (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	500 mg/ml as needed 30-120 drops	24Sep2015	26Sep2015		
		11JUN2015	25SEP2015	Tilidin 100/8 mg	VALORON N	ANALGESICS	Pain-study-rela ted	16 mg	19May2015	18Jun2015		
		11JUN2015	25SEP2015	Oxygesic (Oxycodon)	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	5 mg	10Jun2015	18Jun2015		
		11JUN2015	25SEP2015	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	4500 mg	10Jun2015	12Jul2015		
		11JUN2015	25SEP2015	Novalgine (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	500 mg/ml 30-120 ml as needed	10Jun2015	18Jun2015		
		11JUN2015	25SEP2015	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	4500 mg	24Sep2015	03Oct2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
02/0219	ND basic	11JUN2015	25SEP2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1200 mg	24Sep2015	03Oct2015	
		11JUN2015	25SEP2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1200 mg	24Sep2015	03Oct2015	
		11JUN2015	25SEP2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1200 mg	24Sep2015	03Oct2015	
		11JUN2015	25SEP2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1200 mg	24Sep2015	03Oct2015	
		11JUN2015	25SEP2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1200 mg	24Sep2015	03Oct2015	
02/0220	SC	13AUG2015	-	Oxygesic (Oxycodon)	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	5 mg as needed	12Aug2015	20Aug2015	
		13AUG2015	-	Novalgine (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	500 mg/ml 30-120 drops	12Aug2015	20Aug2015	
		13AUG2015	-	Targin 10/5 mg	TARGIN	ANALGESICS	Pain-study-rela ted	10 mg/5 mg	12Aug2015	17Aug2015	
		13AUG2015	-	Targin 10/5 mg	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-study-rela ted	10 mg/5 mg	12Aug2015	17Aug2015	
		13AUG2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1600 mg	Feb2015	Sep2015	
		13AUG2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1600 mg	Feb2015	Sep2015	
		13AUG2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1600 mg	Feb2015	Sep2015	
		13AUG2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1600 mg	Feb2015	Sep2015	
		13AUG2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1600 mg	Feb2015	Sep2015	
		13AUG2015	-	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	4500 mg	12Aug2015	20Aug2015	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0221	ND plus	01SEP2015	-	Tilidin (Tilidin HCL 100mg/Naloxon 8 mg)	VALORON N /00628301/	ANALGESICS	Pain-study-rela ted	2x1	20Aug2015	Sep2015		
		01SEP2015	-	Novalgin (Novaminsulfon) 500 mg/ml	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	30-120 drops	31Aug2015	Sep2015		
		01SEP2015	-	Orloton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	4500 mg	31Aug2015	Sep2015		
		01SEP2015	-	Oxygenic akut kps	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	1-5 as needed	31Aug2015	Sep2015		
02/0222	ND plus	10SEP2015	-	Tramal 100	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	100 mg	30Aug2015		Yes	
		10SEP2015	-	Sirdalud 2	TIZANIDINE HYDROCHLORIDE	MUSCLE RELAXANTS	Pain-study-rela ted	2 mg	09Sep2015		Yes	
		10SEP2015	-	Sympal injekt	DEXKETOPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	50-150 mg as needed	09Sep2015	15Sep2015		
		10SEP2015	-	Sympal injekt	DEXKETOPROFEN	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	50-150 mg as needed	09Sep2015	15Sep2015		
		10SEP2015	-	Celebrex 200	CELECOXIB	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	200 mg	30Aug2015		Yes	
		10SEP2015	-	Celebrex 200	CELECOXIB	ANTINEOPLASTIC AGENTS	Pain-study-rela ted	200 mg	30Aug2015		Yes	
		10SEP2015	-	Novalgin 500	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	2 g	30Aug2015	15Sep2015		
		10SEP2015	-	Oxygesic 5	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	as needed 5-30 mg	09Sep2015	15Sep2015		
		10SEP2015	-	Lyrica 75	PREGABALIN	ANALGESICS	Pain-study-rela ted	75 mg	30Aug2015		Yes	
		10SEP2015	-	Lyrica 75	PREGABALIN	ANTIEPILEPTICS	Pain-study-rela ted	75 mg	30Aug2015		Yes	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0222	ND plus	10SEP2015	-	Lyrica 75	PREGABALIN	PSYCHOLEPTICS	Pain-study-rela ted	75 mg	30Aug2015		Yes	
02/0223	ND basic	29DEC2015	22MAR2016	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	600 mg	21Mar2016	01Apr2016		
		29DEC2015	22MAR2016	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	600 mg	21Mar2016	01Apr2016		
		29DEC2015	22MAR2016	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	600 mg	21Mar2016	01Apr2016		
		29DEC2015	22MAR2016	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	600 mg	21Mar2016	01Apr2016		
		29DEC2015	22MAR2016	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	600 mg	21Mar2016	01Apr2016		
		29DEC2015	22MAR2016	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	2000 mg	28Dec2015	04Jan2016		
		29DEC2015	22MAR2016	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1500 mg	04Jan2016	02Feb2016		
		29DEC2015	22MAR2016	Ortolon	HYALURONATE SODIUM	OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETA L SYSTEM	Pain-study-rela ted	4500 mg	28Dec2015	04Jan2016		
		29DEC2015	22MAR2016	Ortolon	HYALURONATE SODIUM	UROLOGICALS	Pain-study-rela ted	4500 mg	28Dec2015	04Jan2016		
		29DEC2015	22MAR2016	Ortolon	HYALURONATE SODIUM	OTHER GYNECOLOGICALS	Pain-study-rela ted	4500 mg	28Dec2015	04Jan2016		
		29DEC2015	22MAR2016	Ortolon	HYALURONATE SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted	4500 mg	28Dec2015	04Jan2016		
		29DEC2015	22MAR2016	Ortolon	HYALURONATE SODIUM	PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	Pain-study-rela ted	4500 mg	28Dec2015	04Jan2016		
		29DEC2015	22MAR2016	Ortolon	HYALURONATE SODIUM	VASOPROTECTIVES	Pain-study-rela ted	4500 mg	28Dec2015	04Jan2016		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
02/0223	ND basic	29DEC2015	22MAR2016	Ortolon	HYALURONATE SODIUM	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	4500 mg	28Dec2015	04Jan2016		
		29DEC2015	22MAR2016	Ortolon	HYALURONATE SODIUM	NASAL PREPARATIONS	Pain-study-rela ted	4500 mg	28Dec2015	04Jan2016		
		29DEC2015	22MAR2016	Ortolon	HYALURONATE SODIUM	OPHTHALMOLOGICA LS	Pain-study-rela ted	4500 mg	28Dec2015	04Jan2016		
		29DEC2015	22MAR2016	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1500 mg	21Mar2016	23Mar2016		
		29DEC2015	22MAR2016	Oxygetic akut	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	5 mg	28Dec2015	04Jan2016		
		29DEC2015	22MAR2016	Paracetamol	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1000 mg	30Dec2015	04Jan2016		
02/0224	ND plus	29DEC2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (MedHis no. 01)	1800 mg	27Dec2015	03Jan2016		MH-1
		29DEC2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (MedHis no. 01)	1800 mg	27Dec2015	03Jan2016		MH-1
		29DEC2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (MedHis no. 01)	1800 mg	27Dec2015	03Jan2016		MH-1
		29DEC2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (MedHis no. 01)	1800 mg	27Dec2015	03Jan2016		MH-1
		29DEC2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (MedHis no. 01)	1800 mg	27Dec2015	03Jan2016		MH-1
		29DEC2015	-	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted (MedHis no. 01)	4500 mg	27Dec2015	08Mar2016		MH-1
04/0401	SC	30JUN2015	-	Ibuprofen 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (MedHis no. 08)	1-1-1	01May2015	30Jun2015		MH-8

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
04/0401	SC	30JUN2015	-	Ibuprofen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (MedHis no. 08)	1-1-1	01May2015	30Jun2015		MH-8
		30JUN2015	-	Ibuprofen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (MedHis no. 08)	1-1-1	01May2015	30Jun2015		MH-8
		30JUN2015	-	Ibuprofen 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (MedHis no. 08)	1-1-1	01May2015	30Jun2015		MH-8
		30JUN2015	-	Ibuprofen 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (MedHis no. 08)	1-1-1	01May2015	30Jun2015		MH-8
06/0602	ND plus	23JUL2013	05NOV2013	Novamin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain	3000 MG	23Jul2013	12Aug2013		
		23JUL2013	05NOV2013	Voltaren resinat	DICLOFENAC RESINATE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain	150 MG	23Jul2013	12Aug2013		
		23JUL2013	05NOV2013	Voltaren resinat	DICLOFENAC RESINATE	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain	150 MG	23Jul2013	12Aug2013		
		23JUL2013	05NOV2013	Voltaren resinat	DICLOFENAC RESINATE	OPHTHALMOLOGICA LS	Pain	150 MG	23Jul2013	12Aug2013		
		23JUL2013	05NOV2013	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain	200 MG	23Jul2013	30Jul2013		
		23JUL2013	05NOV2013	Piritramid	PIRITRAMIDE	ANALGESICS	Pain	15 MG	23Jul2013	23Jul2013		
06/0605	ND plus	23JUL2013	05NOV2013	Paracodein	PANADEINE CO	ANALGESICS	Pain	20 GTT	26Jul2013	27Jul2013		
		11DEC2014	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg	11Dec2014		Yes	
		11DEC2014	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1800 mg	11Dec2014		Yes	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0605	ND plus	11DEC2014	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1800 mg	11Dec2014		Yes	
		11DEC2014	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1800 mg	11Dec2014		Yes	
		11DEC2014	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1800 mg	11Dec2014		Yes	
06/0606	SC	16DEC2014	-	Paracetamol	PARACETAMOL	ANALGESICS	Pain-study-rela ted	500 mg	19Dec2014	19Dec2014		
		16DEC2014	-	Dolo Visano	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted (AE no. 09)	1500 mg	27Sep2016	28Sep2016		AE-9
		16DEC2014	-	Methocarbamol	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted (AE no. 26)	1500 mg	17May2017		Yes	AE-26
		16DEC2014	-	Paracetamol	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1500 mg	21Dec2014	Apr2015		
		16DEC2014	-	Diclofenac	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 22)	100 mg/1	Jan2015	Aug2015		AE-22
		16DEC2014	-	Diclofenac	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 22)	100 mg/1	Jan2015	Aug2015		AE-22
		16DEC2014	-	Diclofenac	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 22)	100 mg/1	Jan2015	Aug2015		AE-22
		16DEC2014	-	Diclofenac	DICLOFENAC	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 22)	100 mg/1	Jan2015	Aug2015		AE-22
		16DEC2014	-	Diclofenac	DICLOFENAC	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 22)	100 mg/1	Jan2015	Aug2015		AE-22
		16DEC2014	-	Diclofenac	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 22)	100 mg/1	Jan2015	Aug2015		AE-22
		16DEC2014	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	800 mg	UNK	15Dec2014		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0606	SC	16DEC2014	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	800 mg	UNK	15Dec2014		
		16DEC2014	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	800 mg	UNK	15Dec2014		
		16DEC2014	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	800 mg	UNK	15Dec2014		
		16DEC2014	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	800 mg	UNK	15Dec2014		
		16DEC2014	-	Novalgine (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	500 mg	17Dec2014	17Dec2014		
		16DEC2014	-	Trancolong	FLUPIRTINE MALEATE	ANALGESICS	Pain-study-rela ted (AE no. 22)	400 mg	Jan2015	07Jul2015		AE-22
		16DEC2014	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1800 mg	15Dec2014	20Dec2014		
		16DEC2014	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1800 mg	15Dec2014	20Dec2014		
		16DEC2014	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1800 mg	15Dec2014	20Dec2014		
		16DEC2014	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1800 mg	15Dec2014	20Dec2014		
		16DEC2014	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg	15Dec2014	20Dec2014		
		16DEC2014	-	Paracetamol	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1000 mg	20Dec2014	20Dec2014		
		16DEC2014	-	Flupirtinmaleat	FLUPIRTINE MALEATE	ANALGESICS	Pain-study-rela ted	400 mg	UNK	15Dec2014		
06/0607	ND plus	20JAN2015	15APR2015	Metamizol	METAMIZOLE	ANALGESICS	Pain-study-rela ted (AE no. 09)	1500 mg	11Mar2018	25Mar2018		AE-9
		20JAN2015	15APR2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	600 mg	21Jan2015	14Apr2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0607	ND plus	20JAN2015	15APR2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	600 mg	21Jan2015	14Apr2015		
		20JAN2015	15APR2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	600 mg	21Jan2015	14Apr2015		
		20JAN2015	15APR2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	600 mg	21Jan2015	14Apr2015		
		20JAN2015	15APR2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	600 mg	21Jan2015	14Apr2015		
		20JAN2015	15APR2015	Paracetamol	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1 g	15Apr2015	16Apr2015		
		20JAN2015	15APR2015	Ropivacain	ROPIVACAINE	ANESTHETICS	Pain-study-rela ted (AE no. 11)	50 mg	28Mar2018	28Mar2018		AE-11
		20JAN2015	15APR2015	Ibuprofen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	600 mg	15Apr2015	16Apr2015		
		20JAN2015	15APR2015	Ibuprofen 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	600 mg	15Apr2015	16Apr2015		
		20JAN2015	15APR2015	Ibuprofen 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	600 mg	15Apr2015	16Apr2015		
		20JAN2015	15APR2015	Ibuprofen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	600 mg	15Apr2015	16Apr2015		
		20JAN2015	15APR2015	Ibuprofen 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	600 mg	15Apr2015	16Apr2015		
		20JAN2015	15APR2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 08)	as needed	Oct2016		Yes	AE-8
		20JAN2015	15APR2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 08)	as needed	Oct2016		Yes	AE-8
		20JAN2015	15APR2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 08)	as needed	Oct2016		Yes	AE-8

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0607	ND plus	20JAN2015	15APR2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 08)	as needed	Oct2016		Yes	AE-8
		20JAN2015	15APR2015	Ibuprofen	IBUPROFEN		Pain-study-rela ted (AE no. 08)	as needed	Oct2016		Yes	AE-8
06/0608	SC	29JAN2015	-	Metocloprmid-hydr ochlorid	METOCLOPRAMIDE HYDROCHLORIDE	DRUGS FOR FUNCTIONAL GASTROINTESTINA L DISORDERS	Pain-study-rela ted	300 mg/100 mg	25Jan2015	30Jan2015		
		29JAN2015	-	Dexametason	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	4 mg	25Jan2015	29Jan2015		
		29JAN2015	-	Dexametason	DEXAMETHASONE	VASOPROTECTIVES	Pain-study-rela ted	4 mg	25Jan2015	29Jan2015		
		29JAN2015	-	Dexametason	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Pain-study-rela ted	4 mg	25Jan2015	29Jan2015		
		29JAN2015	-	Dexametason	DEXAMETHASONE	OTOLOGICALS	Pain-study-rela ted	4 mg	25Jan2015	29Jan2015		
		29JAN2015	-	Dexametason	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-study-rela ted	4 mg	25Jan2015	29Jan2015		
		29JAN2015	-	Dexametason	DEXAMETHASONE	OPHTHALMOLOGICA LS	Pain-study-rela ted	4 mg	25Jan2015	29Jan2015		
		29JAN2015	-	Dexametason	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Pain-study-rela ted	4 mg	25Jan2015	29Jan2015		
		29JAN2015	-	Dexametason	DEXAMETHASONE	NASAL PREPARATIONS	Pain-study-rela ted	4 mg	25Jan2015	29Jan2015		
		29JAN2015	-	Dexametason	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-study-rela ted	4 mg	25Jan2015	29Jan2015		
		29JAN2015	-	Dexametason	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted	4 mg	25Jan2015	29Jan2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0608	SC	29JAN2015	-	Dexametason	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Pain-study-rela ted	4 mg	25Jan2015	29Jan2015		
06/0610	ND plus	25JUN2015	08SEP2015	Palexia	TAPENTADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	50 mg/d	24Jun2015	26Jun2015		
		25JUN2015	08SEP2015	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	20 gtt/d 500 mg/d	25Jun2015	26Jun2015		
		25JUN2015	08SEP2015	Palexia	TAPENTADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	50 mg/d	28Jun2015	29Jun2015		
		25JUN2015	08SEP2015	Palexia	TAPENTADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted (AE no. 04)	200 mg	21Jan2016	22Jan2016		AE-4
		25JUN2015	08SEP2015	Metamizol	METAMIZOLE	ANALGESICS	Pain-study-rela ted	40 gtt/d 1000 mg/d	25Jun2015	26Jun2015		
		25JUN2015	08SEP2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 02)	1800 mg	09Sep2015	20Sep2015		AE-2
		25JUN2015	08SEP2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 02)	1800 mg	09Sep2015	20Sep2015		AE-2
		25JUN2015	08SEP2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 02)	1800 mg	09Sep2015	20Sep2015		AE-2
		25JUN2015	08SEP2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 02)	1800 mg	09Sep2015	20Sep2015		AE-2
		25JUN2015	08SEP2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 02)	1800 mg	09Sep2015	20Sep2015		AE-2
		25JUN2015	08SEP2015	Targin	TARGIN	ANALGESICS	Pain-study-rela ted (AE no. 05)	20/10 mg	08Jan2016	18Jan2016		AE-5
		25JUN2015	08SEP2015	Targin	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-study-rela ted (AE no. 05)	20/10 mg	08Jan2016	18Jan2016		AE-5
		25JUN2015	08SEP2015	Novalgin drops (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 04)	600 drops 1.5 g/d	18Jan2016	23Jan2016		AE-4
		25JUN2015	08SEP2015	Capros	MORPHINE SULFATE	ANALGESICS	Pain-study-rela ted	10 mg/d	23Jun2015	30Jun2015		
		25JUN2015	08SEP2015	Novalgin drops (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 05)	160 drops 4.0 g/d	08Jan2016	18Jan2016		AE-5
		25JUN2015	08SEP2015	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted (AE no. 04)	100 mg	19Jan2016	20Jan2016		AE-4

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0610	ND plus	25JUN2015	08SEP2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1800 mg/d	24Jun2015	19Aug2015		
		25JUN2015	08SEP2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg/d	24Jun2015	19Aug2015		
		25JUN2015	08SEP2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1800 mg/d	24Jun2015	19Aug2015		
		25JUN2015	08SEP2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1800 mg/d	24Jun2015	19Aug2015		
		25JUN2015	08SEP2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1800 mg/d	24Jun2015	19Aug2015		
		25JUN2015	08SEP2015	Novalgine (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	20 gtted = 500 mg/d	23Jun2015	23Jun2015		
		25JUN2015	08SEP2015	Palexia	TAPENTADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted (AE no. 04)	50 mg	20Jan2016	20Jan2016		AE-4
06/0612	ND plus	15JUL2015	20OCT2015	Capros	MORPHINE SULFATE	ANALGESICS	Pain-study-rela ted	20 mg	20Oct2015	20Oct2015		
		15JUL2015	20OCT2015	Capros	MORPHINE SULFATE	ANALGESICS	Pain-study-rela ted	20/ug/d	16Jul2015	16Jul2015		
		15JUL2015	20OCT2015	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted	100/8 mg/d	07Jul2015	12Jul2015		
		15JUL2015	20OCT2015	Palexia	/00628301/ TAPENTADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	100 mg/d	17Jul2015	27Jul2015		
		15JUL2015	20OCT2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	400 mg/week	22Oct2015	16May2016		
		15JUL2015	20OCT2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	400 mg/week	22Oct2015	16May2016		
		15JUL2015	20OCT2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	400 mg/week	22Oct2015	16May2016		
		15JUL2015	20OCT2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	400 mg/week	22Oct2015	16May2016		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	400 mg/week	22Oct2015	16May2016	
		15JUL2015	20OCT2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1200 mg/d	07Jul2015	15Jul2015	
		15JUL2015	20OCT2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1200 mg/d	07Jul2015	15Jul2015	
		15JUL2015	20OCT2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1200 mg/d	07Jul2015	15Jul2015	
		15JUL2015	20OCT2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1200 mg/d	07Jul2015	15Jul2015	
		15JUL2015	20OCT2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1200 mg/d	07Jul2015	15Jul2015	
		15JUL2015	20OCT2015	Novalgine (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	4 g/d	07Jul2015	13Jul2015	
		15JUL2015	20OCT2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1800 mg/d	16Jul2015	22Oct2015	
		15JUL2015	20OCT2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1800 mg/d	16Jul2015	22Oct2015	
		15JUL2015	20OCT2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1800 mg/d	16Jul2015	22Oct2015	
		15JUL2015	20OCT2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1800 mg/d	16Jul2015	22Oct2015	
		15JUL2015	20OCT2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg/d	16Jul2015	22Oct2015	
		15JUL2015	20OCT2015	Palexia	TAPENTADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	200 mg/d	13Jul2015	16Jul2015	
		15JUL2015	20OCT2015	Paracetamol	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1 g/d	13Jul2015	14Jul2015	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
06/0612	ND plus	15JUL2015	20OCT2015	Paracetamol 1 g	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1 g/d	16Jul2015	17Jul2015	
06/0613	SC	20JUL2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 02)	600 mg - 1200 mg per week	Feb2017	Sep2019	AE-2
		20JUL2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 02)	600 mg - 1200 mg per week	Feb2017	Sep2019	AE-2
		20JUL2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 02)	600 mg - 1200 mg per week	Feb2017	Sep2019	AE-2
		20JUL2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 02)	600 mg - 1200 mg per week	Feb2017	Sep2019	AE-2
		20JUL2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 02)	600 mg - 1200 mg per week	Feb2017	Sep2019	AE-2
		20JUL2015	-	Arcoxia	ETORICOXIB	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	90 mg/d	Jun2015	11Aug2015	
		20JUL2015	-	Novalgine (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1 g/d	20Jul2015	23Jul2015	
06/0614	ND plus	18AUG2015	18NOV2015	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	200 mg/d	13Aug2015	16Aug2015	
		18AUG2015	18NOV2015	Paracetamol	PARACETAMOL	ANALGESICS	Pain-study-rela ted (AE no. 01)	1 g	16Nov2015	16Nov2015	AE-1
		18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 03)	1600 mg	25Jan2016	22Feb2016	AE-3
		18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 03)	1600 mg	25Jan2016	22Feb2016	AE-3
		18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 03)	1600 mg	25Jan2016	22Feb2016	AE-3
		18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 03)	1600 mg	25Jan2016	22Feb2016	AE-3

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0614	ND plus	18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 03)	1600 mg	25Jan2016	22Feb2016		AE-3
		18AUG2015	18NOV2015	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted (AE no. 05)	100 mg	15Mar2016	17Mar2016		AE-5
		18AUG2015	18NOV2015	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted (AE no. 06)	100 mg	05Jul2016	26Jul2016		AE-6
		18AUG2015	18NOV2015	Tilidin	/00628301/ VALORON N	ANALGESICS	Pain-study-rela ted (AE no. 07)	200 mg	15Aug2016	20Sep2016		AE-7
		18AUG2015	18NOV2015	Tilidin	/00628301/ VALORON N	ANALGESICS	Pain-study-rela ted (AE no. 08)	200 mg	Jan2017	07Oct2019		AE-8
		18AUG2015	18NOV2015	Ropivacain	/00628301/ ROPIVACAINE	ANESTHETICS	Pain-study-rela ted (AE no. 08)	15 mg	24Feb2017	24Feb2017		AE-8
		18AUG2015	18NOV2015	Duloxetine	DULOXETINE	PSYCHOANALEPTIC S	Pain-study-rela ted (AE no. 08)	30 mg	19Feb2018	28Oct2019		AE-8
		18AUG2015	18NOV2015	Duloxetine	DULOXETINE	PSYCHOLEPTICS	Pain-study-rela ted (AE no. 08)	30 mg	19Feb2018	28Oct2019		AE-8
		18AUG2015	18NOV2015	Duloxetine	DULOXETINE	UROLOGICALS	Pain-study-rela ted (AE no. 08)	30 mg	19Feb2018	28Oct2019		AE-8
		18AUG2015	18NOV2015	Duloxetine	DULOXETINE	ANALGESICS	Pain-study-rela ted (AE no. 08)	30 mg	19Feb2018	28Oct2019		AE-8
		18AUG2015	18NOV2015	Urbason	METHYLPREDNISOL ONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-study-rela ted (AE no. 01)	16 mg	16Nov2015	17Nov2015		AE-1
		18AUG2015	18NOV2015	Urbason	METHYLPREDNISOL ONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 01)	16 mg	16Nov2015	17Nov2015		AE-1
		18AUG2015	18NOV2015	Urbason	METHYLPREDNISOL ONE	ANTI-ACNE PREPARATIONS	Pain-study-rela ted (AE no. 01)	16 mg	16Nov2015	17Nov2015		AE-1
		18AUG2015	18NOV2015	Urbason	METHYLPREDNISOL ONE	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 01)	16 mg	16Nov2015	17Nov2015		AE-1
		18AUG2015	18NOV2015	Ropivacain	ROPIVACAINE	ANESTHETICS	Pain-study-rela ted (AE no. 04)	7.5/100 ml	22Feb2016	22Feb2016		AE-4

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0614	ND plus	18AUG2015	18NOV2015	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 05)	60 gtt	11Mar2016	04Apr2016		AE-5
		18AUG2015	18NOV2015	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted (AE no. 06)	150 mg	27Jul2016	14Aug2016		AE-6
					/00628301/ PIRITRAMIDE	ANALGESICS	Pain-study-rela ted (AE no. 07)	UNK	11Aug2016	14Aug2016		AE-7
		18AUG2015	18NOV2015	Dipidolor = Piritramid	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted (AE no. 08)	750 mg	31Jul2017	31Aug2017		AE-8
		18AUG2015	18NOV2015	Triamcinolon acetonid	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-study-rela ted (AE no. 08)	40 mg	24Feb2017	24Feb2017		AE-8
		18AUG2015	18NOV2015	Triamcinolon acetonid	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 08)	40 mg	24Feb2017	24Feb2017		AE-8
		18AUG2015	18NOV2015	Triamcinolon acetonid	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Pain-study-rela ted (AE no. 08)	40 mg	24Feb2017	24Feb2017		AE-8
		18AUG2015	18NOV2015	Triamcinolon acetonid	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 08)	40 mg	24Feb2017	24Feb2017		AE-8
		18AUG2015	18NOV2015	Triamcinolon acetonid	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-study-rela ted (AE no. 08)	40 mg	24Feb2017	24Feb2017		AE-8
		18AUG2015	18NOV2015	Triamcinolon acetonid	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Pain-study-rela ted (AE no. 08)	40 mg	24Feb2017	24Feb2017		AE-8
		18AUG2015	18NOV2015	Triamcinolon acetonid	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 08)	40 mg	24Feb2017	24Feb2017		AE-8
		18AUG2015	18NOV2015	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted (AE no. 08)	100 mg	08Oct2019	28Oct2019		AE-8
					/00628301/ METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	500 mg - 1000 mg	14Aug2015	16Aug2015		
		18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 01)	2400 mg	14Nov2015	22Nov2015		AE-1
		18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 01)	2400 mg	14Nov2015	22Nov2015		AE-1

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0614	ND plus	18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 01)	2400 mg	14Nov2015	22Nov2015		AE-1
		18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 01)	2400 mg	14Nov2015	22Nov2015		AE-1
		18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 01)	2400 mg	14Nov2015	22Nov2015		AE-1
		18AUG2015	18NOV2015	Triamhexal	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-study-rela ted (AE no. 04)	40 mg	22Feb2016	22Feb2016		AE-4
		18AUG2015	18NOV2015	Triamhexal	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 04)	40 mg	22Feb2016	22Feb2016		AE-4
		18AUG2015	18NOV2015	Triamhexal	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Pain-study-rela ted (AE no. 04)	40 mg	22Feb2016	22Feb2016		AE-4
		18AUG2015	18NOV2015	Triamhexal	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 04)	40 mg	22Feb2016	22Feb2016		AE-4
		18AUG2015	18NOV2015	Triamhexal	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Pain-study-rela ted (AE no. 04)	40 mg	22Feb2016	22Feb2016		AE-4
		18AUG2015	18NOV2015	Triamhexal	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 04)	40 mg	22Feb2016	22Feb2016		AE-4
		18AUG2015	18NOV2015	Triamhexal	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-study-rela ted (AE no. 04)	40 mg	22Feb2016	22Feb2016		AE-4
		18AUG2015	18NOV2015	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted (AE no. 05)	100 mg	11Mar2016	11Mar2016		AE-5
		18AUG2015	18NOV2015	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted (AE no. 05)	50/4 mg	15Mar2016	18Mar2016		AE-5
		18AUG2015	18NOV2015	Ibuprofen	/00628301/ IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 07)	1200 mg	15Aug2016	20Sep2016		AE-7
		18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 07)	1200 mg	15Aug2016	20Sep2016		AE-7

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0614	ND plus	18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 07)	1200 mg	15Aug2016	20Sep2016		AE-7
		18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 07)	1200 mg	15Aug2016	20Sep2016		AE-7
		18AUG2015	18NOV2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 07)	1200 mg	15Aug2016	20Sep2016		AE-7
		18AUG2015	18NOV2015	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted (AE no. 08)	100 mg	21Sep2016	14Oct2016		AE-8
		18AUG2015	18NOV2015	Novaminsulfon	/00628301/ METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 08)	1000 mg	01Sep2017	28Oct2019		AE-8
		18AUG2015	18NOV2015	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 01)	1500 mg	16Nov2015	18Nov2015		AE-1
		18AUG2015	18NOV2015	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted (AE no. 04 05)	100/8 mg	22Feb2016	14Mar2016		
		18AUG2015	18NOV2015	Tramal	/00628301/ TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted (AE no. 05)	200 mg	12Mar2016	14Mar2016		AE-5
		18AUG2015	18NOV2015	Metamizol	METAMIZOLE	ANALGESICS	Pain-study-rela ted (AE no. 06)	2250 mg	11Jul2016	11Jul2016		AE-6
		18AUG2015	18NOV2015	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted (AE no. 08)	50 mg	15Oct2016	Jan2017		AE-8
		18AUG2015	18NOV2015	Amitriptylin	/00628301/ AMITRIPTYLINE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted (AE no. 08)	20 mg	29Sep2017	18Feb2018		AE-8
		18AUG2015	18NOV2015	Amitriptylin	AMITRIPTYLINE HYDROCHLORIDE	PSYCHOANALEPTIC S	Pain-study-rela ted (AE no. 08)	20 mg	29Sep2017	18Feb2018		AE-8
06/0615	ND basic	25AUG2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	600 mg - 1200 mg	11Aug2015	Sep2015		
		25AUG2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	600 mg - 1200 mg	11Aug2015	Sep2015		
		25AUG2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	600 mg - 1200 mg	11Aug2015	Sep2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
06/0615	ND basic	25AUG2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	600 mg - 1200 mg	11Aug2015	Sep2015	
		25AUG2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	600 mg - 1200 mg	11Aug2015	Sep2015	
06/0616		09NOV2015	-	Voltaren resinat	DICLOFENAC RESINATE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	150 mg	03Nov2015	06Nov2015	
		09NOV2015	-	Voltaren resinat	DICLOFENAC RESINATE	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	150 mg	03Nov2015	06Nov2015	
		09NOV2015	-	Voltaren resinat	DICLOFENAC RESINATE	OPHTHALMOLOGICA LS	Pain-study-rela ted	150 mg	03Nov2015	06Nov2015	
		09NOV2015	-	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	300 mg	04Nov2015	07Nov2015	
		09NOV2015	-	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	1500 mg	11Nov2015	Dec2015	
		09NOV2015	-	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	3000 mg	04Nov2015	07Nov2015	
		09NOV2015	-	Capros	MORPHINE SULFATE	ANALGESICS	Pain-study-rela ted	20 mg	10Nov2015	11Nov2015	
		09NOV2015	-	Piritramid	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	7.5 mg	07Nov2015	11Nov2015	
		09NOV2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg	06Nov2015	Dec2015	
		09NOV2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1800 mg	06Nov2015	Dec2015	
		09NOV2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1800 mg	06Nov2015	Dec2015	
		09NOV2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1800 mg	06Nov2015	Dec2015	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0616		09NOV2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1800 mg	06Nov2015	Dec2015		
		09NOV2015	-	Oxycodon	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	30 mg	11Nov2015		Yes	
06/0617	ND plus	22DEC2015	-	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	100 mg	18Dec2015	22Dec2015		
		22DEC2015	-	Capros	MORPHINE SULFATE	ANALGESICS	Pain-study-rela ted	10 mg	18Dec2015	03Jan2016		
		22DEC2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1800 mg	18Dec2015	28Dec2015		
		22DEC2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg	18Dec2015	28Dec2015		
		22DEC2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1800 mg	18Dec2015	28Dec2015		
		22DEC2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATO RY AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1800 mg	18Dec2015	28Dec2015		
		22DEC2015	-	Novalgine (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	2 g	18Dec2015	22Dec2015		
06/0619	ND basic	23FEB2016	10MAY2016	Novalgine (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	500 mg	23Feb2016	23Feb2016		
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 04)	600 mg	02Aug2016	02Aug2016		AE-4
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 04)	600 mg	02Aug2016	02Aug2016		AE-4
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 04)	600 mg	02Aug2016	02Aug2016		AE-4

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0619	ND basic	23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 04)	600 mg	02Aug2016	02Aug2016		AE-4
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 04)	600 mg	02Aug2016	02Aug2016		AE-4
		23FEB2016	10MAY2016	Voltaren resinat	DICLOFENAC RESINATE	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	150 mg	Jan2016	08Mar2016		
		23FEB2016	10MAY2016	Voltaren resinat	DICLOFENAC RESINATE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	150 mg	Jan2016	08Mar2016		
		23FEB2016	10MAY2016	Voltaren resinat	DICLOFENAC RESINATE	OPHTHALMOLOGICA LS	Pain-study-rela ted	150 mg	Jan2016	08Mar2016		
		23FEB2016	10MAY2016	Voltaren	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 03)	150 mg	12May2016	02Jun2016		AE-3
		23FEB2016	10MAY2016	Voltaren	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 03)	150 mg	12May2016	02Jun2016		AE-3
		23FEB2016	10MAY2016	Voltaren	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 03)	150 mg	12May2016	02Jun2016		AE-3
		23FEB2016	10MAY2016	Voltaren	DICLOFENAC	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 03)	150 mg	12May2016	02Jun2016		AE-3
		23FEB2016	10MAY2016	Voltaren	DICLOFENAC	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 03)	150 mg	12May2016	02Jun2016		AE-3
		23FEB2016	10MAY2016	Voltaren	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 03)	150 mg	12May2016	02Jun2016		AE-3
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 07)	1200 mg	28Aug2017	14Oct2017		AE-7

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0619	ND basic	23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 07)	1200 mg	28Aug2017	14Oct2017		AE-7
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 07)	1200 mg	28Aug2017	14Oct2017		AE-7
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 07)	1200 mg	28Aug2017	14Oct2017		AE-7
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 07)	1200 mg	28Aug2017	14Oct2017		AE-7
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	400 mg	UNK	Aug2020		
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	400 mg	UNK	Aug2020		
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	400 mg	UNK	Aug2020		
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	400 mg	UNK	Aug2020		
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	400 mg	UNK	Aug2020		
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 07)	600 mg	15Oct2017	30Oct2017		AE-7
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 07)	600 mg	15Oct2017	30Oct2017		AE-7
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 07)	600 mg	15Oct2017	30Oct2017		AE-7
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 07)	600 mg	15Oct2017	30Oct2017		AE-7
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 07)	600 mg	15Oct2017	30Oct2017		AE-7

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0619	ND basic	23FEB2016	10MAY2016	Cortison	CORTISONE ACETATE	HOMEOPATHIC PREPARATION	Pain-study-rela ted (AE no. 07)	UNK	11Sep2017	11Sep2017		AE-7
		23FEB2016	10MAY2016	Cortison	CORTISONE ACETATE	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 07)	UNK	11Sep2017	11Sep2017		AE-7
		23FEB2016	10MAY2016	Cortison	CORTISONE ACETATE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-study-rela ted (AE no. 07)	UNK	11Sep2017	11Sep2017		AE-7
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1200 mg - 1800 mg per week	UNK	Aug2020		
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1200 mg - 1800 mg per week	UNK	Aug2020		
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1200 mg - 1800 mg per week	UNK	Aug2020		
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1200 mg - 1800 mg per week	UNK	Aug2020		
		23FEB2016	10MAY2016	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1200 mg - 1800 mg per week	UNK	Aug2020		
		23FEB2016	10MAY2016	Tilidin / Naloxon	NALOXONE W/TILIDINE	ANALGESICS	Pain-study-rela ted (AE no. 07)	100 mg/8 mg	12Sep2017	14Oct2017		AE-7
		23FEB2016	10MAY2016	Tilidin / Naloxon	NALOXONE W/TILIDINE	ALL OTHER THERAPEUTIC PRODUCTS	Pain-study-rela ted (AE no. 07)	100 mg/8 mg	12Sep2017	14Oct2017		AE-7
06/0620	SC	24FEB2016	-	Voltaren resinat	DICLOFENAC RESINATE	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	150 mg	Aug2015	07Mar2016		
		24FEB2016	-	Voltaren resinat	DICLOFENAC RESINATE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	150 mg	Aug2015	07Mar2016		
		24FEB2016	-	Voltaren resinat	DICLOFENAC RESINATE	OPHTHALMOLOGICA LS	Pain-study-rela ted	150 mg	Aug2015	07Mar2016		
		24FEB2016	-	Diclofenac	DICLOFENAC	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 06)	150 mg	18Sep2020	21Sep2020		AE-6

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
06/0620	SC	24FEB2016	-	Diclofenac	DICLOFENAC	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 06)	150 mg	18Sep2020	21Sep2020		AE-6
		24FEB2016	-	Diclofenac	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 06)	150 mg	18Sep2020	21Sep2020		AE-6
		24FEB2016	-	Diclofenac	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 06)	150 mg	18Sep2020	21Sep2020		AE-6
		24FEB2016	-	Diclofenac	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 06)	150 mg	18Sep2020	21Sep2020		AE-6
		24FEB2016	-	Diclofenac	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 06)	150 mg	18Sep2020	21Sep2020		AE-6
07/0701	ND plus	06NOV2014	20JAN2015	Arcoxia 90 mg	ETORICOXIB	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	90 mg 1x/d	05Nov2014	11Nov2014		
		06NOV2014	20JAN2015	Paracetamol	PARACETAMOL	ANALGESICS	Pain-study-rela ted	500 mg 3 x/d	20Jan2015	21Jan2015		
		06NOV2014	20JAN2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	600 mg 3 x/d	06Nov2014	08Nov2014		
		06NOV2014	20JAN2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	600 mg 3 x/d	06Nov2014	08Nov2014		
		06NOV2014	20JAN2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	600 mg 3 x/d	06Nov2014	08Nov2014		
		06NOV2014	20JAN2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	600 mg 3 x/d	06Nov2014	08Nov2014		
		06NOV2014	20JAN2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	600 mg 3 x/d	06Nov2014	08Nov2014		
		06NOV2014	20JAN2015	Paracetamol	PARACETAMOL	ANALGESICS	Pain-study-rela ted	750 mg 1 x/d	05Nov2014	11Nov2014		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
07/0702	SC	20JAN2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela	600 mg 3 x/d	13Jan2015	02Mar2015	
		20JAN2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela	600 mg 3 x/d	13Jan2015	02Mar2015	
		20JAN2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela	600 mg 3 x/d	13Jan2015	02Mar2015	
		20JAN2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela	600 mg 3 x/d	13Jan2015	02Mar2015	
		20JAN2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela	600 mg 3 x/d	13Jan2015	02Mar2015	
		20JAN2015	-	Novaminsulfon	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela	1 g 4 x/d	13Jan2015	19Jan2015	
		20JAN2015	-	Targin	TARGIN	ANALGESICS	Pain-study-rela	10/5 mg p.o. 2x/d	20Jan2015	23Jan2015	
		20JAN2015	-	Targin	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-study-rela	10/5 mg p.o. 2x/d	20Jan2015	23Jan2015	
		20JAN2015	-	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela	750 mg 2 tbl. 3x/d	13Jan2015	02Mar2015	
		20JAN2015	-	Ortoton 750 mg Tbl.	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela	750 mg 1-0-1/d	02Mar2015		Yes
07/0703	ND plus	03MAR2015	19MAY2015	Ibuprofen 400 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela	1-0-0/d	23Mar2015	29Mar2015	
		03MAR2015	19MAY2015	Ibuprofen 400 mg	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela	1-0-0/d	23Mar2015	29Mar2015	
		03MAR2015	19MAY2015	Ibuprofen 400 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela	1-0-0/d	23Mar2015	29Mar2015	
		03MAR2015	19MAY2015	Ibuprofen 400 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela	1-0-0/d	23Mar2015	29Mar2015	
		03MAR2015	19MAY2015	Ibuprofen 400 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela	1-0-0/d	23Mar2015	29Mar2015	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
07/0703	ND plus	03MAR2015	19MAY2015	Novalgin 500 mg	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	0-2-2/d	01Jun2015	02Jun2015	
07/0704	ND basic	16JUL2015	08OCT2015	Diclofenac 50 mg	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	1-1-1	Jun2015	16Jul2015	
		16JUL2015	08OCT2015	Diclofenac 50 mg	DICLOFENAC	THROAT PREPARATIONS	Pain-study-rela ted	1-1-1	Jun2015	16Jul2015	
		16JUL2015	08OCT2015	Diclofenac 50 mg	DICLOFENAC	OPHTHALMOLOGICA LS	Pain-study-rela ted	1-1-1	Jun2015	16Jul2015	
		16JUL2015	08OCT2015	Diclofenac 50 mg	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1-1-1	Jun2015	16Jul2015	
		16JUL2015	08OCT2015	Diclofenac 50 mg	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1-1-1	Jun2015	16Jul2015	
		16JUL2015	08OCT2015	Diclofenac 50 mg	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted	1-1-1	Jun2015	16Jul2015	
		16JUL2015	08OCT2015	Diclofenac	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	150 mg	08Oct2015	10Oct2015	
		16JUL2015	08OCT2015	Diclofenac	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted	150 mg	08Oct2015	10Oct2015	
		16JUL2015	08OCT2015	Diclofenac	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	150 mg	08Oct2015	10Oct2015	
		16JUL2015	08OCT2015	Diclofenac	DICLOFENAC	OPHTHALMOLOGICA LS	Pain-study-rela ted	150 mg	08Oct2015	10Oct2015	
		16JUL2015	08OCT2015	Diclofenac	DICLOFENAC	THROAT PREPARATIONS	Pain-study-rela ted	150 mg	08Oct2015	10Oct2015	
		16JUL2015	08OCT2015	Diclofenac	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	150 mg	08Oct2015	10Oct2015	
		16JUL2015	08OCT2015	Novaminsulfon	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	4 g	09Oct2015	10Oct2015	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
07/0704	ND basic	16JUL2015	08OCT2015	Novaminsulfon 500 mg	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1-1-1-1	16Jul2015	18Jul2015		
07/0705		13AUG2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1200 mg	07Aug2015		Yes	
		13AUG2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1200 mg	07Aug2015		Yes	
		13AUG2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1200 mg	07Aug2015		Yes	
		13AUG2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1200 mg	07Aug2015		Yes	
		13AUG2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1200 mg	07Aug2015		Yes	
07/0706	SC	01DEC2015	-	Tilidin 50 mg ret.	TILIDINE	ANALGESICS	Pain-study-rela ted	2-0-2	02Dec2015	03Dec2015		
		01DEC2015	-	Novaminsulfon 40	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	4 x 1 g	24Nov2015	28Nov2015		
		01DEC2015	-	Tilidin 50 mg ret.	TILIDINE	ANALGESICS	Pain-study-rela ted	1-0-1	04Dec2015	05Dec2015		
		01DEC2015	-	Ortoton 750 mg	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	2-2-2	24Nov2015	03Dec2015		
		01DEC2015	-	Tilidin 50 mg ret.	TILIDINE	ANALGESICS	Pain-study-rela ted	1-0-2	01Dec2015	01Dec2015		
		01DEC2015	-	Ibuprofen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	3x1	24Nov2015	28Nov2015		
		01DEC2015	-	Ibuprofen 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	3x1	24Nov2015	28Nov2015		
		01DEC2015	-	Ibuprofen 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	3x1	24Nov2015	28Nov2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
07/0706	SC	01DEC2015	-	Ibuprofen 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela	3x1	24Nov2015	28Nov2015		
		01DEC2015	-	Ibuprofen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela	3x1	24Nov2015	28Nov2015		
07/0707		-	-	Arcoxia 90 mg	ETORICOXIB	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela	90 mg	15Jan2016		Yes	
		-	-	Novaminsulfon	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela	1 gr 3x/d	14Feb2016		Yes	
		-	-	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela	250 mg 3x/d	14Feb2016		Yes	
08/0801	SC	03NOV2014	-	Novalgine (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela	1.5 gr	14Jan2015		Yes	
		03NOV2014	-	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	Pain-study-rela	4 mg	03Nov2014	03Nov2014		
		03NOV2014	-	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	Pain-study-rela	4 mg	03Nov2014	03Nov2014		
		03NOV2014	-	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-study-rela	4 mg	03Nov2014	03Nov2014		
		03NOV2014	-	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Pain-study-rela	4 mg	03Nov2014	03Nov2014		
		03NOV2014	-	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	Pain-study-rela	4 mg	03Nov2014	03Nov2014		
		03NOV2014	-	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Pain-study-rela	4 mg	03Nov2014	03Nov2014		
		03NOV2014	-	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Pain-study-rela	4 mg	03Nov2014	03Nov2014		
		03NOV2014	-	Fortecortin	DEXAMETHASONE	OTOLOGICALS	Pain-study-rela	4 mg	03Nov2014	03Nov2014		
		03NOV2014	-	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-study-rela	4 mg	03Nov2014	03Nov2014		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0801	SC	03NOV2014	-	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS	Pain-study-rela ted	4 mg	03Nov2014	03Nov2014		
		03NOV2014	-	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Pain-study-rela ted	4 mg	03Nov2014	03Nov2014		
		03NOV2014	-	Perfalgan	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1 gr	03Nov2014	03Nov2014		
		03NOV2014	-	Gabapentin	GABAPENTIN	ANALGESICS	Pain-study-rela ted	900 mg	14Jan2015		Yes	
		03NOV2014	-	Gabapentin	GABAPENTIN	OTHER NERVOUS SYSTEM DRUGS	Pain-study-rela ted	900 mg	14Jan2015		Yes	
		03NOV2014	-	Gabapentin	GABAPENTIN	ANTIEPILEPTICS	Pain-study-rela ted	900 mg	14Jan2015		Yes	
		03NOV2014	-	Targin	TARGIN	ANALGESICS	Pain-study-rela ted	10/5 mg	04Nov2014	25Nov2014		
		03NOV2014	-	Targin	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-study-rela ted	10/5 mg	04Nov2014	25Nov2014		
		03NOV2014	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1.2 gr	25Nov2014	16Dec2014		
		03NOV2014	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1.2 gr	25Nov2014	16Dec2014		
		03NOV2014	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1.2 gr	25Nov2014	16Dec2014		
		03NOV2014	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1.2 gr	25Nov2014	16Dec2014		
		03NOV2014	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1.2 gr	25Nov2014	16Dec2014		
		03NOV2014	-	Targin	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-study-rela ted	20/10 mg	01Oct2014	03Nov2014		
		03NOV2014	-	Targin	TARGIN	ANALGESICS	Pain-study-rela ted	20/10 mg	01Oct2014	03Nov2014		
08/0802	ND plus	27NOV2014	04MAR2015	Diclofenac	DICLOFENAC	OPHTHALMOLOGICA LS	Pain-study-rela ted	150 mg	15Sep2014	05Dec2014		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo ing? MH/AE
08/0802	ND plus	27NOV2014	04MAR2015	Diclofenac	DICLOFENAC	THROAT PREPARATIONS	Pain-study-rela ted	150 mg	15Sep2014	05Dec2014	
		27NOV2014	04MAR2015	Diclofenac	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	150 mg	15Sep2014	05Dec2014	
		27NOV2014	04MAR2015	Diclofenac	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	150 mg	15Sep2014	05Dec2014	
		27NOV2014	04MAR2015	Diclofenac	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted	150 mg	15Sep2014	05Dec2014	
		27NOV2014	04MAR2015	Diclofenac	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	150 mg	15Sep2014	05Dec2014	
		27NOV2014	04MAR2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	400 mg	26Nov2014	26Nov2014	
		27NOV2014	04MAR2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	400 mg	26Nov2014	26Nov2014	
		27NOV2014	04MAR2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	400 mg	26Nov2014	26Nov2014	
		27NOV2014	04MAR2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	400 mg	26Nov2014	26Nov2014	
		27NOV2014	04MAR2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	400 mg	26Nov2014	26Nov2014	
		27NOV2014	04MAR2015	Dexamethason	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted	4 mg	27Nov2014	27Nov2014	
		27NOV2014	04MAR2015	Dexamethason	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Pain-study-rela ted	4 mg	27Nov2014	27Nov2014	
		27NOV2014	04MAR2015	Dexamethason	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-study-rela ted	4 mg	27Nov2014	27Nov2014	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
08/0802	ND plus	27NOV2014	04MAR2015	Dexamethason	DEXAMETHASONE	VASOPROTECTIVES	Pain-study-rela ted	4 mg	27Nov2014	27Nov2014	
		27NOV2014	04MAR2015	Dexamethason	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	4 mg	27Nov2014	27Nov2014	
		27NOV2014	04MAR2015	Dexamethason	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Pain-study-rela ted	4 mg	27Nov2014	27Nov2014	
		27NOV2014	04MAR2015	Dexamethason	DEXAMETHASONE	OTOLOGICALS	Pain-study-rela ted	4 mg	27Nov2014	27Nov2014	
		27NOV2014	04MAR2015	Dexamethason	DEXAMETHASONE	NASAL PREPARATIONS	Pain-study-rela ted	4 mg	27Nov2014	27Nov2014	
		27NOV2014	04MAR2015	Dexamethason	DEXAMETHASONE	OPHTHALMOLOGICA LS	Pain-study-rela ted	4 mg	27Nov2014	27Nov2014	
		27NOV2014	04MAR2015	Dexamethason	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-study-rela ted	4 mg	27Nov2014	27Nov2014	
		27NOV2014	04MAR2015	Dexamethason	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Pain-study-rela ted	4 mg	27Nov2014	27Nov2014	
08/0803	ND basic	25FEB2015	16JUN2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	400 mg	01Feb2015	01Apr2015	
		25FEB2015	16JUN2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	400 mg	01Feb2015	01Apr2015	
		25FEB2015	16JUN2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	400 mg	01Feb2015	01Apr2015	
		25FEB2015	16JUN2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	400 mg	01Feb2015	01Apr2015	
		25FEB2015	16JUN2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	400 mg	01Feb2015	01Apr2015	
		25FEB2015	16JUN2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 01)	1200 mg	19Jun2015	27Jun2015	AE-1

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0803	ND basic	25FEB2015	16JUN2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 01)	1200 mg	19Jun2015	27Jun2015		AE-1
		25FEB2015	16JUN2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 01)	1200 mg	19Jun2015	27Jun2015		AE-1
		25FEB2015	16JUN2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 01)	1200 mg	19Jun2015	27Jun2015		AE-1
		25FEB2015	16JUN2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 01)	1200 mg	19Jun2015	27Jun2015		AE-1
		25FEB2015	16JUN2015	Perfalgan	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1 g	25Feb2015	25Feb2015		
08/0804	ND plus	03JUN2015	21AUG2015	Tramadol	TRAMADOL	ANALGESICS	Pain-study-rela ted	400 mg	01Jun2015	01Jun2015		
		03JUN2015	21AUG2015	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	2.5 gr	01Jun2015	01Jun2015		
		03JUN2015	21AUG2015	Novalgin Metamizole	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1 gr	03Jun2015	03Jun2015		
		03JUN2015	21AUG2015	Tramadol	TRAMADOL	ANALGESICS	Pain-study-rela ted	100 mg	29May2015	05Jun2015		
		03JUN2015	21AUG2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	2.4 gr	22May2015	29May2015		
		03JUN2015	21AUG2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	2.4 gr	22May2015	29May2015		
		03JUN2015	21AUG2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	2.4 gr	22May2015	29May2015		
		03JUN2015	21AUG2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	2.4 gr	22May2015	29May2015		
		03JUN2015	21AUG2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	2.4 gr	22May2015	29May2015		
		03JUN2015	21AUG2015	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted	40 mg	01Jun2015	01Jun2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0804	ND plus	03JUN2015	21AUG2015	Fortecortin	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Pain-study-rela ted	40 mg	01Jun2015	01Jun2015		
		03JUN2015	21AUG2015	Fortecortin	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-study-rela ted	40 mg	01Jun2015	01Jun2015		
		03JUN2015	21AUG2015	Fortecortin	DEXAMETHASONE	NASAL PREPARATIONS	Pain-study-rela ted	40 mg	01Jun2015	01Jun2015		
		03JUN2015	21AUG2015	Fortecortin	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-study-rela ted	40 mg	01Jun2015	01Jun2015		
		03JUN2015	21AUG2015	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA LS	Pain-study-rela ted	40 mg	01Jun2015	01Jun2015		
		03JUN2015	21AUG2015	Fortecortin	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Pain-study-rela ted	40 mg	01Jun2015	01Jun2015		
		03JUN2015	21AUG2015	Fortecortin	DEXAMETHASONE	VASOPROTECTIVES	Pain-study-rela ted	40 mg	01Jun2015	01Jun2015		
		03JUN2015	21AUG2015	Fortecortin	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	40 mg	01Jun2015	01Jun2015		
		03JUN2015	21AUG2015	Fortecortin	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Pain-study-rela ted	40 mg	01Jun2015	01Jun2015		
		03JUN2015	21AUG2015	Fortecortin	DEXAMETHASONE	OTOLOGICALS	Pain-study-rela ted	40 mg	01Jun2015	01Jun2015		
		03JUN2015	21AUG2015	Piritramid	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	7.5 mg	03Jun2015	03Jun2015		
		03JUN2015	21AUG2015	Novalgine Metamizole	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1.5 gr	03Jun2015	10Jun2015		
08/0805	ND basic	25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1.2 g	15Apr2015	14Sep2015		
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1.2 g	15Apr2015	14Sep2015		
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1.2 g	15Apr2015	14Sep2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0805	ND basic	25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1.2 g	15Apr2015	14Sep2015		
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1.2 g	15Apr2015	14Sep2015		
		25JUN2015	22SEP2015	Perfalgan	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1000 mg	25Jun2015	25Jun2015		
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 01)	400 mg	04Oct2015	10Dec2015		AE-1
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 01)	400 mg	04Oct2015	10Dec2015		AE-1
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 01)	400 mg	04Oct2015	10Dec2015		AE-1
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 01)	400 mg	04Oct2015	10Dec2015		AE-1
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 01)	400 mg	04Oct2015	10Dec2015		AE-1
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	400 mg	27Jun2015	27Jun2015		
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	400 mg	27Jun2015	27Jun2015		
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	400 mg	27Jun2015	27Jun2015		
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	400 mg	27Jun2015	27Jun2015		
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	400 mg	27Jun2015	27Jun2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0805	ND basic	25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 02)	1.8 gr	08Jul2016	15Aug2016		AE-2
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 02)	1.8 gr	08Jul2016	15Aug2016		AE-2
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 02)	1.8 gr	08Jul2016	15Aug2016		AE-2
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 02)	1.8 gr	08Jul2016	15Aug2016		AE-2
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 02)	1.8 gr	08Jul2016	15Aug2016		AE-2
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 01)	1.8 gr	01Oct2015	03Oct2015		AE-1
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 01)	1.8 gr	01Oct2015	03Oct2015		AE-1
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 01)	1.8 gr	01Oct2015	03Oct2015		AE-1
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 01)	1.8 gr	01Oct2015	03Oct2015		AE-1
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 01)	1.8 gr	01Oct2015	03Oct2015		AE-1
		25JUN2015	22SEP2015	Novalgin 500 mg Tbl	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 04)	2000 mg/d	28Jul2016	15Aug2016		AE-4
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 08)	600 mg	15Aug2017	15Aug2017		AE-8
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 08)	600 mg	15Aug2017	15Aug2017		AE-8
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 08)	600 mg	15Aug2017	15Aug2017		AE-8

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0805	ND basic	25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 08)	600 mg	15Aug2017	15Aug2017		AE-8
		25JUN2015	22SEP2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 08)	600 mg	15Aug2017	15Aug2017		AE-8
08/0806	ND plus	08JUL2015	29SEP2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	400 mg	16Jun2015	07Jul2015		
		08JUL2015	29SEP2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	400 mg	16Jun2015	07Jul2015		
		08JUL2015	29SEP2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	400 mg	16Jun2015	07Jul2015		
		08JUL2015	29SEP2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	400 mg	16Jun2015	07Jul2015		
		08JUL2015	29SEP2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	400 mg	16Jun2015	07Jul2015		
		08JUL2015	29SEP2015	Paracetamol	PARACETAMOL	ANALGESICS	Pain-study-rela ted	500 mg	13Jul2015	15Jul2015		
		08JUL2015	29SEP2015	Voltaren res.	DICLOFENAC RESINATE	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	75 mg	16Jun2015	07Jul2015		
		08JUL2015	29SEP2015	Voltaren res.	DICLOFENAC RESINATE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	75 mg	16Jun2015	07Jul2015		
		08JUL2015	29SEP2015	Voltaren res.	DICLOFENAC RESINATE	OPHTHALMOLOGICA LS	Pain-study-rela ted	75 mg	16Jun2015	07Jul2015		
		08JUL2015	29SEP2015	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	500 mg	09Jul2015	09Jul2015		
		08JUL2015	29SEP2015	Perfalgan	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1000 mg	08Jul2015	08Jul2015		
		08JUL2015	29SEP2015	Diclofenac	DICLOFENAC	OPHTHALMOLOGICA LS	Pain-study-rela ted	150 mg	08Jul2015	12Jul2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0806	ND plus	08JUL2015	29SEP2015	Diclofenac	DICLOFENAC	THROAT PREPARATIONS	Pain-study-rela ted	150 mg	08Jul2015	12Jul2015		
		08JUL2015	29SEP2015	Diclofenac	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	150 mg	08Jul2015	12Jul2015		
		08JUL2015	29SEP2015	Diclofenac	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	150 mg	08Jul2015	12Jul2015		
		08JUL2015	29SEP2015	Diclofenac	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	150 mg	08Jul2015	12Jul2015		
		08JUL2015	29SEP2015	Diclofenac	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted	150 mg	08Jul2015	12Jul2015		
08/0807	ND plus	19NOV2015	02FEB2016	Diclofenac	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted	150 mg	09Nov2015	20Nov2015		
		19NOV2015	02FEB2016	Diclofenac	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	150 mg	09Nov2015	20Nov2015		
		19NOV2015	02FEB2016	Diclofenac	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	150 mg	09Nov2015	20Nov2015		
		19NOV2015	02FEB2016	Diclofenac	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	150 mg	09Nov2015	20Nov2015		
		19NOV2015	02FEB2016	Diclofenac	DICLOFENAC	OPHTHALMOLOGICA LS	Pain-study-rela ted	150 mg	09Nov2015	20Nov2015		
		19NOV2015	02FEB2016	Diclofenac	DICLOFENAC	THROAT PREPARATIONS	Pain-study-rela ted	150 mg	09Nov2015	20Nov2015		
		19NOV2015	02FEB2016	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1.8 g	02Nov2015	30Dec2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0807	ND plus	19NOV2015	02FEB2016	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1.8 g	02Nov2015	30Dec2015		
		19NOV2015	02FEB2016	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1.8 g	02Nov2015	30Dec2015		
		19NOV2015	02FEB2016	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1.8 g	02Nov2015	30Dec2015		
		19NOV2015	02FEB2016	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1.8 g	02Nov2015	30Dec2015		
		19NOV2015	02FEB2016	Paracetamol	PARACETAMOL	ANALGESICS	Pain-study-rela ted	3 g	19Nov2015	24Nov2015		
		19NOV2015	02FEB2016	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	400 mg	02Feb2016	02Feb2016		
		19NOV2015	02FEB2016	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	400 mg	02Feb2016	02Feb2016		
		19NOV2015	02FEB2016	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	400 mg	02Feb2016	02Feb2016		
		19NOV2015	02FEB2016	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	400 mg	02Feb2016	02Feb2016		
		19NOV2015	02FEB2016	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	400 mg	02Feb2016	02Feb2016		
		19NOV2015	02FEB2016	Pantozol (Pantoprazol)	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Pain-study-rela ted	40 mg	09Nov2015	30Dec2015		
		19NOV2015	02FEB2016	Methocarbamol	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	750 mg	02Nov2015	09Nov2015		
		19NOV2015	02FEB2016	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 01)	1.8 g	03Mar2016	20Mar2016		AE-1
		19NOV2015	02FEB2016	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 01)	1.8 g	03Mar2016	20Mar2016		AE-1
		19NOV2015	02FEB2016	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 01)	1.8 g	03Mar2016	20Mar2016		AE-1

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0807	ND plus	19NOV2015	02FEB2016	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 01)	1.8 g	03Mar2016	20Mar2016		AE-1
		19NOV2015	02FEB2016	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 01)	1.8 g	03Mar2016	20Mar2016		AE-1
		19NOV2015	02FEB2016	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	200 mg	11Nov2015	12Nov2015		
		19NOV2015	02FEB2016	Piritramid	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	21.5 mg	19Nov2015	19Nov2015		
		19NOV2015	02FEB2016	Novalgine (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1.5 gr	02Nov2015	23Nov2015		
		19NOV2015	02FEB2016	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Pain-study-rela ted (AE no. 01)	40 mg	11Mar2016	20Mar2016		AE-1
08/0808	SC	03DEC2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1.8 gr	03Dec2015	20Dec2015		
		03DEC2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1.8 gr	03Dec2015	20Dec2015		
		03DEC2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATO RY AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1.8 gr	03Dec2015	20Dec2015		
		03DEC2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1.8 gr	03Dec2015	20Dec2015		
		03DEC2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1.8 gr	03Dec2015	20Dec2015		
		03DEC2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 04)	1.2 g	27Mar2017	31Mar2017		AE-4
		03DEC2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 04)	1.2 g	27Mar2017	31Mar2017		AE-4

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0808	SC	03DEC2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 04)	1.2 g	27Mar2017	31Mar2017		AE-4
		03DEC2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 04)	1.2 g	27Mar2017	31Mar2017		AE-4
		03DEC2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 04)	1.2 g	27Mar2017	31Mar2017		AE-4
		03DEC2015	-	Metamizol	METAMIZOLE	ANALGESICS	Pain-study-rela ted	1 gr	03Dec2015	03Dec2015		
		03DEC2015	-	Pantoprazol	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Pain-study-rela ted	40 mg	03Dec2015	20Dec2015		
		03DEC2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 02)	400 mg	23Apr2016	30Apr2016		AE-2
		03DEC2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 02)	400 mg	23Apr2016	30Apr2016		AE-2
		03DEC2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 02)	400 mg	23Apr2016	30Apr2016		AE-2
		03DEC2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 02)	400 mg	23Apr2016	30Apr2016		AE-2
		03DEC2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 02)	400 mg	23Apr2016	30Apr2016		AE-2
		03DEC2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 04)	400 mg	01Apr2017	19Apr2017		AE-4
		03DEC2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 04)	400 mg	01Apr2017	19Apr2017		AE-4
		03DEC2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 04)	400 mg	01Apr2017	19Apr2017		AE-4
		03DEC2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 04)	400 mg	01Apr2017	19Apr2017		AE-4

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
08/0808	SC	03DEC2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 04)	400 mg	01Apr2017	19Apr2017		AE-4
		03DEC2015	-	Piritramid	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	7.5 mg	03Dec2015	03Dec2015		
		03DEC2015	-	Paracetamol	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1 gr	03Dec2015	03Dec2015		
09/0901	SC	30OCT2014	-	Ibuprophen 400 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1-0-0	26Dec2014	16Apr2015		
		30OCT2014	-	Ibuprophen 400 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1-0-0	26Dec2014	16Apr2015		
		30OCT2014	-	Ibuprophen 400 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1-0-0	26Dec2014	16Apr2015		
		30OCT2014	-	Ibuprophen 400 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1-0-0	26Dec2014	16Apr2015		
		30OCT2014	-	Ibuprophen 400 mg	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1-0-0	26Dec2014	16Apr2015		
		30OCT2014	-	Ibuhexal	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1-1-1 400 mg	01Sep2014	25Dec2014		
		30OCT2014	-	Ibuhexal	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1-1-1 400 mg	01Sep2014	25Dec2014		
		30OCT2014	-	Ibuhexal	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1-1-1 400 mg	01Sep2014	25Dec2014		
		30OCT2014	-	Ibuhexal	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1-1-1 400 mg	01Sep2014	25Dec2014		
		30OCT2014	-	Ibuhexal	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1-1-1 400 mg	01Sep2014	25Dec2014		
		30OCT2014	-	Metamizol 500 mg	METAMIZOLE	ANALGESICS	Pain-study-rela ted	2-2-2-2	30Oct2014	26Dec2014		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
09/0901	SC	30OCT2014	-	Ibuprophen 400 mg	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	as needed app. 3 x week 1 x 400 mg	16Apr2015	17Dec2016	
		30OCT2014	-	Ibuprophen 400 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	as needed app. 3 x week 1 x 400 mg	16Apr2015	17Dec2016	
		30OCT2014	-	Ibuprophen 400 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	as needed app. 3 x week 1 x 400 mg	16Apr2015	17Dec2016	
		30OCT2014	-	Ibuprophen 400 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	as needed app. 3 x week 1 x 400 mg	16Apr2015	17Dec2016	
		30OCT2014	-	Ibuprophen 400 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	as needed app. 3 x week 1 x 400 mg	16Apr2015	17Dec2016	
		30OCT2014	-	Pregabatin	PREGABALIN	ANTIEPILEPTICS	Pain-study-rela ted	1-0-1 75 mg	01Sep2014	26Dec2015	
		30OCT2014	-	Pregabatin	PREGABALIN	PSYCHOLEPTICS	Pain-study-rela ted	1-0-1 75 mg	01Sep2014	26Dec2015	
		30OCT2014	-	Pregabatin	PREGABALIN	ANALGESICS	Pain-study-rela ted	1-0-1 75 mg	01Sep2014	26Dec2015	
		30OCT2014	-	Metamizol	METAMIZOLE	ANALGESICS	Pain-study-rela ted	1-0-1 500 mg	01Sep2014	29Oct2015	
09/0903	ND plus	20NOV2014	-	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	1-0-1 100 mg	14Oct2014	19Nov2014	
		20NOV2014	-	Metamizol	METAMIZOLE	ANALGESICS	Pain-study-rela ted	1-1-1-1 500 mg	19Nov2014	19Jan2015	
		20NOV2014	-	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted (AE no. 01)	50 mg 1-1-1	20Jan2015	24Jan2015	AE-1
		20NOV2014	-	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted	1-0-1 100 mg	19Nov2014	19Jan2015	
		20NOV2014	-	Tramal	/00628301/ TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted (AE no. 01)	1-1-1 100 mg	27Jan2015	01Feb2015	AE-1

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0904	ND basic	09FEB2015	21MAY2015	Tilidin 100/8	VALORON N	ANALGESICS	Pain-study-rela ted	1-0-1	20Jan2015	20Feb2015		
		09FEB2015	21MAY2015	Novalgine 1 g	/00628301/ METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1-1-1-1	20Jan2015	20Feb2015		
09/0905	ND plus	19MAR2015	25JUN2015	Oxygesic	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	10-0-10 10 mg	14Mar2015	20Mar2015		
		19MAR2015	25JUN2015	Pregabalin 25 mg Tbl.	PREGABALIN	ANALGESICS	Pain-study-rela ted (AE no. 03)	1-1-1	01Sep2018	09Sep2018		AE-3
		19MAR2015	25JUN2015	Pregabalin 25 mg Tbl.	PREGABALIN	PSYCHOLEPTICS	Pain-study-rela ted (AE no. 03)	1-1-1	01Sep2018	09Sep2018		AE-3
		19MAR2015	25JUN2015	Pregabalin 25 mg Tbl.	PREGABALIN	ANTIEPILEPTICS	Pain-study-rela ted (AE no. 03)	1-1-1	01Sep2018	09Sep2018		AE-3
		19MAR2015	25JUN2015	Ibuprophen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	600-600-600 mg	14Mar2015	16Mar2015		
		19MAR2015	25JUN2015	Ibuprophen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	600-600-600 mg	14Mar2015	16Mar2015		
		19MAR2015	25JUN2015	Ibuprophen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	600-600-600 mg	14Mar2015	16Mar2015		
		19MAR2015	25JUN2015	Ibuprophen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	600-600-600 mg	14Mar2015	16Mar2015		
		19MAR2015	25JUN2015	Ibuprophen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	600-600-600 mg	14Mar2015	16Mar2015		
		19MAR2015	25JUN2015	Tilidin 50 mg	VALORON N	ANALGESICS	Pain-study-rela ted (AE no. 01)	1-0-1	21Mar2015	19Apr2015		AE-1
		19MAR2015	25JUN2015	Ibuflam 600 mg Tabl.	/00628301/ IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 03)	1-1-1	07Sep2018	29Oct2018		AE-3
		19MAR2015	25JUN2015	Ibuflam 600 mg Tabl.	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 03)	1-1-1	07Sep2018	29Oct2018		AE-3
		19MAR2015	25JUN2015	Ibuflam 600 mg Tabl.	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 03)	1-1-1	07Sep2018	29Oct2018		AE-3

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0905	ND plus	19MAR2015	25JUN2015	Ibuflam 600 mg Tabl.	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 03)	1-1-1	07Sep2018	29Oct2018		AE-3
		19MAR2015	25JUN2015	Ibuflam 600 mg Tabl.	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 03)	1-1-1	07Sep2018	29Oct2018		AE-3
		19MAR2015	25JUN2015	Buccain 0.25% 5 ml	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain-study-rela ted (AE no. 03)	1-0-0	26Sep2018	26Sep2018		AE-3
		19MAR2015	25JUN2015	Buccain 0.25% 5 ml	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 03)	1-0-0	26Sep2018	26Sep2018		AE-3
		19MAR2015	25JUN2015	Ibuflam 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 03)	600 mg 1-0-0	30Oct2018	18Feb2019		AE-3
		19MAR2015	25JUN2015	Ibuflam 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 03)	600 mg 1-0-0	30Oct2018	18Feb2019		AE-3
		19MAR2015	25JUN2015	Ibuflam 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 03)	600 mg 1-0-0	30Oct2018	18Feb2019		AE-3
		19MAR2015	25JUN2015	Ibuflam 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 03)	600 mg 1-0-0	30Oct2018	18Feb2019		AE-3
		19MAR2015	25JUN2015	Ibuflam 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 03)	600 mg 1-0-0	30Oct2018	18Feb2019		AE-3
		19MAR2015	25JUN2015	Tilidin Tabl. 50 mg/4 mg	VALORON N /00628301/	ANALGESICS	Pain-study-rela ted (AE no. 04)	1-0-1	06Apr2019	19Apr2019		AE-4
		19MAR2015	25JUN2015	Novalgine 500 mg	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1-0-0-0	20Apr2015	11Nov2015		
		19MAR2015	25JUN2015	Tilidin AL 50 mg/4 mg Tabl.	VALORON N /00628301/	ANALGESICS	Pain-study-rela ted (AE no. 03)	2-0-2	07Sep2018	05Apr2019		AE-3
		19MAR2015	25JUN2015	Buccain 0.25% 5 ml	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 03)	1-0-0	28Sep2018	28Sep2018		AE-3
		19MAR2015	25JUN2015	Buccain 0.25% 5 ml	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain-study-rela ted (AE no. 03)	1-0-0	28Sep2018	28Sep2018		AE-3
		19MAR2015	25JUN2015	Novalgine drops (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 03)	40 as needed 1-2 weeks	30Oct2018	07Jan2019		AE-3

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0905	ND plus	19MAR2015	25JUN2015	Novalgin Tabl. 500 mg	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 04)	as needed app. every 2nd day	06Apr2019	20Apr2019		AE-4
		19MAR2015	25JUN2015	Novaminsulfon	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1-1-1-1 gr	17Mar2015	19Apr2015		
		19MAR2015	25JUN2015	Novalgin drops (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 03)	40-40-40	21Sep2018	29Oct2018		AE-3
		19MAR2015	25JUN2015	Buccain 0.25% 5 ml	BUPIVACAINE HYDROCHLORIDE	ANESTHETICS	Pain-study-rela ted (AE no. 03)	1-0-0	01Oct2018	01Oct2018		AE-3
		19MAR2015	25JUN2015	Buccain 0.25% 5 ml	BUPIVACAINE HYDROCHLORIDE	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 03)	1-0-0	01Oct2018	01Oct2018		AE-3
		19MAR2015	25JUN2015	Novalgin 500 mg Tabl. (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 04)	1g-1gr-1gr-1g	11Mar2019	05Apr2019		AE-4
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 03)	1-0-0	26Sep2018	26Sep2018		AE-3
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-study-rela ted (AE no. 03)	1-0-0	26Sep2018	26Sep2018		AE-3
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Pain-study-rela ted (AE no. 03)	1-0-0	26Sep2018	26Sep2018		AE-3
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Pain-study-rela ted (AE no. 03)	1-0-0	26Sep2018	26Sep2018		AE-3
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 03)	1-0-0	26Sep2018	26Sep2018		AE-3
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-study-rela ted (AE no. 03)	1-0-0	26Sep2018	26Sep2018		AE-3
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 03)	1-0-0	28Sep2018	28Sep2018		AE-3
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-study-rela ted (AE no. 03)	1-0-0	28Sep2018	28Sep2018		AE-3
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 03)	1-0-0	28Sep2018	28Sep2018		AE-3

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0905	ND plus	19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Pain-study-rela ted (AE no. 03)	1-0-0	28Sep2018	28Sep2018		AE-3
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Pain-study-rela ted (AE no. 03)	1-0-0	28Sep2018	28Sep2018		AE-3
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 03)	1-0-0	28Sep2018	28Sep2018		AE-3
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-study-rela ted (AE no. 03)	1-0-0	28Sep2018	28Sep2018		AE-3
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 03)	1-0-0	01Oct2018	01Oct2018		AE-3
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-study-rela ted (AE no. 03)	1-0-0	01Oct2018	01Oct2018		AE-3
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	NASAL PREPARATIONS	Pain-study-rela ted (AE no. 03)	1-0-0	01Oct2018	01Oct2018		AE-3
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	VASOPROTECTIVES	Pain-study-rela ted (AE no. 03)	1-0-0	01Oct2018	01Oct2018		AE-3
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 03)	1-0-0	01Oct2018	01Oct2018		AE-3
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-study-rela ted (AE no. 03)	1-0-0	01Oct2018	01Oct2018		AE-3
		19MAR2015	25JUN2015	Triam Hexal 20 mg PRT L4 re	TRIAMCINOLONE ACETONIDE	CORTICOSTEROIDS / DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 03)	1-0-0	01Oct2018	01Oct2018		AE-3
09/0906		-	-	Voltaren Tbl. 50 mg	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1-0-1	18Mar2015		Yes	
		-	-	Voltaren Tbl. 50 mg	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted	1-0-1	18Mar2015		Yes	
		-	-	Voltaren Tbl. 50 mg	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1-0-1	18Mar2015		Yes	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0906				Voltaren Tbl. 50 mg	DICLOFENAC	THROAT PREPARATIONS	Pain-study-rela ted	1-0-1	18Mar2015		Yes	
				Voltaren Tbl. 50 mg	DICLOFENAC	OPHTHALMOLOGICALS	Pain-study-rela ted	1-0-1	18Mar2015		Yes	
				Voltaren Tbl. 50 mg	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	1-0-1	18Mar2015		Yes	
09/0907	SC	15APR2015	-	Tilidin 100mg/8mg	VALORON N	ANALGESICS	Pain-study-rela ted	1-0-1	16Apr2015	17Apr2015		
		15APR2015	-	Novalgin 500 mg	/00628301/ METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	2-2-2-2	16Apr2015	17Apr2015		
09/0908	ND basic	07MAY2015	06AUG2015	Metamizol	METAMIZOLE	ANALGESICS	Pain-study-rela ted	4 x 1 gr.	02May2015	11May2015		
		07MAY2015	06AUG2015	Tilidin 100/8 mg, Tilidin-HCL 100mg,	VALORON N	ANALGESICS	Pain-study-rela ted	1-0-1	08May2015	11May2015		
		07MAY2015	06AUG2015	Naloxon-HCL 8 mg Oxycodon	/00628301/ OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	2 x 20 mg	02May2015	08May2015		
09/0909	ND plus	12MAY2015	13AUG2015	Novalgin 500 mg	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 01)	2-2-2-2	19Aug2015	20Aug2015		AE-1
		12MAY2015	13AUG2015	Oxycodon	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	10mg-0-30mg	05May2015	11May2015		
		12MAY2015	13AUG2015	Novalgin 500 mg	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	2-2-2-2	05May2015	16May2015		
		12MAY2015	13AUG2015	Novalgin 500 mg	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 01)	1-0-1	18Aug2015	19Aug2015		AE-1
09/0910	ND plus	01SEP2015	-	Metamizol	METAMIZOLE	ANALGESICS	Pain-study-rela ted	1 g 1-1-1-1	26Jul2015		Yes	
		01SEP2015	-	Morphinsulfat	MORPHINE SULFATE	ANALGESICS	Pain-study-rela ted	10 mg as needed	26Aug2015		Yes	
		01SEP2015	-	Pregabalin	PREGABALIN	ANALGESICS	Pain-study-rela ted	75 mg 0-0-1	26Aug2015		Yes	
		01SEP2015	-	Pregabalin	PREGABALIN	PSYCHOLEPTICS	Pain-study-rela ted	75 mg 0-0-1	26Aug2015		Yes	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0910	ND plus	01SEP2015	-	Pregabalin	PREGABALIN	ANTIEPILEPTICS	Pain-study-rela ted	75 mg 0-0-1	26Aug2015		Yes	
		01SEP2015	-	Oxycodon	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	10 mg 1-0-1	26Aug2015	02Sep2015		
		01SEP2015	-	Tilidin 100 mg	VALORON N	ANALGESICS	Pain-study-rela ted	1-0-1	02Sep2015		Yes	
/00628301/												
09/0911	ND plus	19OCT2015	14JAN2016	Ibuhexal 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (MedHis no. 01)	as needed	15Dec2014	18Oct2015		MH-1
		19OCT2015	14JAN2016	Ibuhexal 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (MedHis no. 01)	as needed	15Dec2014	18Oct2015		MH-1
		19OCT2015	14JAN2016	Ibuhexal 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (MedHis no. 01)	as needed	15Dec2014	18Oct2015		MH-1
		19OCT2015	14JAN2016	Ibuhexal 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (MedHis no. 01)	as needed	15Dec2014	18Oct2015		MH-1
		19OCT2015	14JAN2016	Ibuhexal 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (MedHis no. 01)	as needed	15Dec2014	18Oct2015		MH-1
		19OCT2015	14JAN2016	Tilidin 100 mg	VALORON N	ANALGESICS	Pain-study-rela ted	1-0-1	19Oct2015	22Oct2015		
		19OCT2015	14JAN2016	Paracetamol 500 mg	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1-1-1-1	21Oct2015	22Oct2015		
		19OCT2015	14JAN2016	Tilidin 50 mg	VALORON N	ANALGESICS	Pain-study-rela ted	as needed 1x daily	23Oct2015	06Nov2015		
		19OCT2015	14JAN2016	Metamizol 500 mg Tab	METAMIZOLE	ANALGESICS	Pain-study-rela ted	2-2-2-2	19Oct2015	20Oct2015		
/00628301/												
09/0912	ND plus	20OCT2015	21JAN2016	Diclophenac 75 mg	DICLOFENAC SODIUM	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	1-0-1	19Sep2015	19Oct2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
09/0912	ND plus	20OCT2015	21JAN2016	Diclophenac 75 mg	DICLOFENAC SODIUM	THROAT PREPARATIONS	Pain-study-rela ted	1-0-1	19Sep2015	19Oct2015	
		20OCT2015	21JAN2016	Diclophenac 75 mg	DICLOFENAC SODIUM	OPHTHALMOLOGICALS	Pain-study-rela ted	1-0-1	19Sep2015	19Oct2015	
		20OCT2015	21JAN2016	Diclophenac 75 mg	DICLOFENAC SODIUM	OTHER DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted	1-0-1	19Sep2015	19Oct2015	
		20OCT2015	21JAN2016	Diclophenac 75 mg	DICLOFENAC SODIUM	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1-0-1	19Sep2015	19Oct2015	
		20OCT2015	21JAN2016	Diclophenac 75 mg	DICLOFENAC SODIUM	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1-0-1	19Sep2015	19Oct2015	
		20OCT2015	21JAN2016	Tilidin 100 mg	VALORON N	ANALGESICS	Pain-study-rela ted	1-0-1	20Oct2015	25Oct2015	
		20OCT2015	21JAN2016	Novalgin 500 mg Tabl.	/00628301/ METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 01)	2-2-2	22Jan2016	24Jan2016	AE-1
		20OCT2015	21JAN2016	Ortoton (Methocarbamol 750 mg)	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	1-0-1	19Sep2015	09Oct2015	
		20OCT2015	21JAN2016	Novalgin 500 mg Tabl.	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 01)	1-0-1	25Jan2016	28Jan2016	AE-1
		20OCT2015	21JAN2016	Novalgin 500 mg Tbl	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	2-2-2	09Oct2015	19Oct2015	
		20OCT2015	21JAN2016	Novalgin 500 mg	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1-1-1	27Oct2015	29Oct2015	
09/0913	ND basic	30NOV2015	18FEB2016	Pregabalin 25 mg	PREGABALIN	PSYCHOLEPTICS	Pain-study-rela ted (AE no. 01)	0-0-2	04Dec2015	06Dec2015	AE-1
		30NOV2015	18FEB2016	Pregabalin 25 mg	PREGABALIN	ANTIEPILEPTICS	Pain-study-rela ted (AE no. 01)	0-0-2	04Dec2015	06Dec2015	AE-1
		30NOV2015	18FEB2016	Pregabalin 25 mg	PREGABALIN	ANALGESICS	Pain-study-rela ted (AE no. 01)	0-0-2	04Dec2015	06Dec2015	AE-1
		30NOV2015	18FEB2016	Pregabalin beta 75 mg	PREGABALIN	ANTIEPILEPTICS	Pain-study-rela ted (AE no. 05)	0-0-1	07Dec2015	05Feb2016	AE-5

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0913	ND basic	30NOV2015	18FEB2016	Pregabalin beta 75 mg	PREGABALIN	PSYCHOLEPTICS	Pain-study-rela ted (AE no. 05)	0-0-1	07Dec2015	05Feb2016		AE-5
		30NOV2015	18FEB2016	Pregabalin beta 75 mg	PREGABALIN	ANALGESICS	Pain-study-rela ted (AE no. 05)	0-0-1	07Dec2015	05Feb2016		AE-5
		30NOV2015	18FEB2016	Metamizol 500 mg Tabl.	METAMIZOLE	ANALGESICS	Pain-study-rela ted	2-2-2-2	30Nov2015	06Dec2015		
		30NOV2015	18FEB2016	Novaminsulfon 500 mg	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 05)	20-0-20 drops	07Dec2015	10Dec2015		AE-5
		30NOV2015	18FEB2016	Tilidin 100 mg Tabl.	VALORON N	ANALGESICS	Pain-study-rela ted	1-0-1	30Nov2015	06Dec2015		
		30NOV2015	18FEB2016	Tilidin 50 mg/4 mg	VALORON N	ANALGESICS	Pain-study-rela ted (AE no. 05)	0-0-1	07Dec2015	17Dec2015		AE-5
09/0914	SC	06JAN2016	-	Metamizol/Novalgin 500 mg	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1-1-1-1	21Jan2016	22Feb2016		
		06JAN2016	-	Metamizol 500 mg	METAMIZOLE	ANALGESICS	Pain-study-rela ted	2-2-2-2	07Jan2016	20Jan2016		
		06JAN2016	-	Tilidin 100/8 mg	VALORON N	ANALGESICS	Pain-study-rela ted	1-0-1	07Jan2016	15Feb2016		
09/0915	ND basic	06JAN2016	24MAR2016	Novalgin 500 mg	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1-1-1-1	11Jan2016	17Jan2016		
		06JAN2016	24MAR2016	Diclophenac AL50	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 04)	2-0-2	14Jul2020	22Jul2020		AE-4
		06JAN2016	24MAR2016	Diclophenac AL50	DICLOFENAC	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 04)	2-0-2	14Jul2020	22Jul2020		AE-4
		06JAN2016	24MAR2016	Diclophenac AL50	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 04)	2-0-2	14Jul2020	22Jul2020		AE-4
		06JAN2016	24MAR2016	Diclophenac AL50	DICLOFENAC	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 04)	2-0-2	14Jul2020	22Jul2020		AE-4

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
09/0915	ND basic	06JAN2016	24MAR2016	Diclophenac AL50	DICLOFENAC	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 04)	2-0-2	14Jul2020	22Jul2020		AE-4
		06JAN2016	24MAR2016	Diclophenac AL50	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 04)	2-0-2	14Jul2020	22Jul2020		AE-4
		06JAN2016	24MAR2016	Tilidin 100 mg/8 g	VALORON N /00628301/	ANALGESICS	Pain-study-rela ted (AE no. 01)	0-0-1	24Mar2016	24Mar2016		AE-1
		06JAN2016	24MAR2016	Methocarbamol AL 750 mg	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted (AE no. 04)	2-2-2	14Jul2020	18Jul2020		AE-4
		06JAN2016	24MAR2016	Metamizol 500 mg	METAMIZOLE	ANALGESICS	Pain-study-rela ted	2-2-2-2	07Jan2016	10Jan2016		
		06JAN2016	24MAR2016	Tilidin 100 mg/8 g	VALORON N /00628301/	ANALGESICS	Pain-study-rela ted (AE no. 01)	1-0-1	25Mar2016	25Mar2016		AE-1
		06JAN2016	24MAR2016	Tilidin 100/8 mg	VALORON N /00628301/	ANALGESICS	Pain-study-rela ted	1-0-1	07Jan2016	10Jan2016		
09/0916	SC	23FEB2016	-	Tilidin 100/8 mg	VALORON N /00628301/	ANALGESICS	Pain-study-rela ted	1-0-0	01Feb2016	22Feb2016		
		23FEB2016	-	Tilidin 50 mg	VALORON N /00628301/	ANALGESICS	Pain-study-rela ted (AE no. 02)	0-1-0	02Mar2016	15Mar2016		AE-2
		23FEB2016	-	Tilidin 100/8 mg	VALORON N /00628301/	ANALGESICS	Pain-study-rela ted	1-0-1	23Feb2016	23Feb2016		
		23FEB2016	-	Metamizol 500 mg	METAMIZOLE	ANALGESICS	Pain-study-rela ted	1-1-1-1	24Feb2016	27Feb2016		
		23FEB2016	-	Metamizol	METAMIZOLE	ANALGESICS	Pain-study-rela ted	2-2-2-2	23Feb2016	23Feb2016		
		23FEB2016	-	Tilidin 100/8 mg	VALORON N /00628301/	ANALGESICS	Pain-study-rela ted	1-0-0	24Feb2016	27Feb2016		
10/1001		-	-	Lyrica (Pregabalin) 50 mg	PREGABALIN	ANALGESICS	Pain-study-rela ted	5x tgl	02Nov2015	22Nov2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
10/1001		-	-	Lyrica (Pregabalin) 50 mg	PREGABALIN	ANTIEPILEPTICS	Pain-study-rela ted	5x tgl	02Nov2015	22Nov2015		
		-	-	Lyrica (Pregabalin) 50 mg	PREGABALIN	PSYCHOLEPTICS	Pain-study-rela ted	5x tgl	02Nov2015	22Nov2015		
		-	-	Lyrica (Pregabalin) 50 mg	PREGABALIN	ANTIEPILEPTICS	Pain-study-rela ted	QID	23Nov2015		Yes	
		-	-	Lyrica (Pregabalin) 50 mg	PREGABALIN	PSYCHOLEPTICS	Pain-study-rela ted	QID	23Nov2015		Yes	
		-	-	Lyrica (Pregabalin) 50 mg	PREGABALIN	ANALGESICS	Pain-study-rela ted	QID	23Nov2015		Yes	
		-	-	Novalgin (Metamizol) 500 mg	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	Q6h 20 drops	02Nov2015		Yes	
		-	-	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted	BID 15 drops	02Nov2015	07Nov2015		
/00628301/												
11/1101	ND plus	13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1800 mg	20Dec2014	27Jan2015		
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg	20Dec2014	27Jan2015		
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1800 mg	20Dec2014	27Jan2015		
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1800 mg	20Dec2014	27Jan2015		
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1800 mg	20Dec2014	27Jan2015		
		13JAN2015	31MAR2015	Paracetamol	PARACETAMOL	ANALGESICS	Pain-study-rela ted (AE no. 05)	1 g i.v.	27Sep2017	27Sep2017		AE-5

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1101	ND plus	13JAN2015	31MAR2015	Arcoxia	ETORICOXIB	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 09)	90 mg	28Jun2019	01Aug2019		AE-9
		13JAN2015	31MAR2015	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	4 g/50 NaCl 2.1 mL/h i.v.	13Jan2015	14Jan2015		
		13JAN2015	31MAR2015	Lyrica	PREGABALIN	ANTIEPILEPTICS	Pain-study-rela ted	75 mg	27Dec2014	12Jan2015		
		13JAN2015	31MAR2015	Lyrica	PREGABALIN	PSYCHOLEPTICS	Pain-study-rela ted	75 mg	27Dec2014	12Jan2015		
		13JAN2015	31MAR2015	Lyrica	PREGABALIN	ANALGESICS	Pain-study-rela ted	75 mg	27Dec2014	12Jan2015		
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 06)	600 mg as needed	Mar2018	30Jul2019		AE-6
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 06)	600 mg as needed	Mar2018	30Jul2019		AE-6
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 06)	600 mg as needed	Mar2018	30Jul2019		AE-6
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 06)	600 mg as needed	Mar2018	30Jul2019		AE-6
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 06)	600 mg as needed	Mar2018	30Jul2019		AE-6
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 10)	1800 mg	01Aug2019	Aug2019		AE-10
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted (AE no. 10)	1800 mg	01Aug2019	Aug2019		AE-10
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 10)	1800 mg	01Aug2019	Aug2019		AE-10
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted (AE no. 10)	1800 mg	01Aug2019	Aug2019		AE-10

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1101	ND plus	13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 10)	1800 mg	01Aug2019	Aug2019		AE-10
		13JAN2015	31MAR2015	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted	150 mg	02Jan2015	12Jan2015		
		13JAN2015	31MAR2015	Ibuprofen	/00628301/ IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1800 mg	31Mar2015	02Apr2015		
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg	31Mar2015	02Apr2015		
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1800 mg	31Mar2015	02Apr2015		
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1800 mg	31Mar2015	02Apr2015		
		13JAN2015	31MAR2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1800 mg	31Mar2015	02Apr2015		
		13JAN2015	31MAR2015	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted	100 mg	27Dec2014	02Jan2015		
		13JAN2015	31MAR2015	Novalgin (Metamizol)	/00628301/ METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 05)	4 g/50 ml NaCl 2.1 ml/h i.v.	27Sep2017	28Sep2017		
		13JAN2015	31MAR2015	Tramaldol	TRAMADOL	ANALGESICS	Pain-study-rela ted (AE no. 10)	200 mg	01Aug2019	Aug2019		
11/1102	ND basic	20APR2015	28JUL2015	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1800 mg	Mar2015	21Apr2015		
		20APR2015	28JUL2015	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1800 mg	Mar2015	21Apr2015		
		20APR2015	28JUL2015	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1800 mg	Mar2015	21Apr2015		
		20APR2015	28JUL2015	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1800 mg	Mar2015	21Apr2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1102	ND basic	20APR2015	28JUL2015	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1800 mg	Mar2015	21Apr2015		
		20APR2015	28JUL2015	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	160 drops	14Apr2015	21Apr2015		
		20APR2015	28JUL2015	Targin 10/5 Naloxon 5.45 mg Oxycodon Hydrochlorid 10 mg	TARGIN	ANALGESICS	Pain-study-rela ted	1 x daily	15Apr2015	19Apr2015		
		20APR2015	28JUL2015	Targin 10/5 Naloxon 5.45 mg Oxycodon Hydrochlorid 10 mg	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-study-rela ted	1 x daily	15Apr2015	19Apr2015		
11/1103	SC	03AUG2015	-	Arcoxia	ETORICOXIB	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 01)	90 mg	13Aug2015	23Nov2015		AE-1
		03AUG2015	-	Targin	TARGIN	ANALGESICS	Pain-study-rela ted (AE no. 01+14)	30 mg	03Sep2015	24Oct2015		
		03AUG2015	-	Targin	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-study-rela ted (AE no. 01+14)	30 mg	03Sep2015	24Oct2015		
		03AUG2015	-	Ortoton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted (AE no. 05)	750 mg as needed	Dec2017	03Jan2018		AE-5
		03AUG2015	-	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 07)	3000 mg	04Jan2018	11Jan2018		AE-7
		03AUG2015	-	Targin	TARGIN	ANALGESICS	Pain-study-rela ted	20/10 2x per day	11Jan2018		Yes	
		03AUG2015	-	Targin	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-study-rela ted	20/10 2x per day	11Jan2018		Yes	
		03AUG2015	-	Oxygesic (Oxycodon)	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted (AE no. 01)	40 mg	11Aug2015	12Aug2015		AE-1

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1103	SC	03AUG2015	-	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 01+14)	1.5 g	27Aug2015	25Oct2015		
		03AUG2015	-	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 04)	500 mg as needed	Jan2017	03Jan2018		AE-4
		03AUG2015	-	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 07)	40 drops	03Jan2018	03Jan2018		AE-7
		03AUG2015	-	Sevredol	MORPHINE SULFATE	ANALGESICS	Pain-study-rela ted (AE no. 07)	up to 40 mg	04Jan2018	13Jan2018		AE-7
		03AUG2015	-	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	4000 mg	12Jan2018	13Feb2018		
		03AUG2015	-	Tramadol	TRAMADOL	ANALGESICS	Pain-study-rela ted (AE no. 10)	100 mg as needed	Mar2018		Yes	AE-10
		03AUG2015	-	Tramal retard	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	300 mg	May2015	10Aug2015		
		03AUG2015	-	Targin	TARGIN	ANALGESICS	Pain-study-rela ted (AE no. 01+14)	50 mg	13Aug2015	02Sep2015		
		03AUG2015	-	Targin	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-study-rela ted (AE no. 01+14)	50 mg	13Aug2015	02Sep2015		
		03AUG2015	-	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted (AE no. 04)	100 mg as needed	Jan2017	03Jan2018		AE-4
		03AUG2015	-	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted (AE no. 07)	100 mg i.v.	03Jan2018	03Jan2018		AE-7
		03AUG2015	-	Ortroton	METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted	3000 mg	04Jan2018		Yes	
		03AUG2015	-	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 07)	4 g / 50 ml NaCl i.v.	10Jan2018	11Jan2018		AE-7
		03AUG2015	-	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted (AE no. 09)	500 mg	13Feb2018	14Feb2018		AE-9
		03AUG2015	-	Tramal	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted (AE no. 09)	100 mg as needed	14Feb2018	25Feb2018		AE-9
		03AUG2015	-	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 01+14)	4 g	11Aug2015	26Aug2015		
		03AUG2015	-	Dipidolor	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted (AE no. 07)	1 Amp i.v. 15 mg	03Jan2018	03Jan2018		AE-7

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
11/1103	SC	03AUG2015	-	Tramal long	TRAMADOL HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted (AE no. 07)	200 mg	04Jan2018	11Jan2018		AE-7
		03AUG2015	-	Novalgine (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 09)	4 g	13Feb2018	14Feb2018		AE-9
		03AUG2015	-	Novalgine (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 09)	3000 mg	14Feb2018	UNK		AE-9
11/1104	ND plus	07MAR2016	08JUN2016	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1200 mg	Jan2016	11Mar2016		
		07MAR2016	08JUN2016	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1200 mg	Jan2016	11Mar2016		
		07MAR2016	08JUN2016	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1200 mg	Jan2016	11Mar2016		
		07MAR2016	08JUN2016	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1200 mg	Jan2016	11Mar2016		
		07MAR2016	08JUN2016	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1200 mg	Jan2016	11Mar2016		
		07MAR2016	08JUN2016	Paracetamol	PARACETAMOL	ANALGESICS	Pain-study-rela ted	2000 mg	Jan2016	11Mar2016		
12/1201	ND plus	07SEP2015	01DEC2015	Periradicular Infiltration S1 with Volon 40 mg	TRIAMCINOLONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-study-rela ted	40 mg	28Aug2015	28Aug2015		
		07SEP2015	01DEC2015	Periradicular Infiltration S1 with Volon 40 mg	TRIAMCINOLONE	CORTICOSTEROIDS , DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted	40 mg	28Aug2015	28Aug2015		
		07SEP2015	01DEC2015	Periradicular Infiltration S1 with Volon 40 mg	TRIAMCINOLONE	VASOPROTECTIVES	Pain-study-rela ted	40 mg	28Aug2015	28Aug2015		
		07SEP2015	01DEC2015	Periradicular Infiltration S1 with Volon 40 mg	TRIAMCINOLONE	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	40 mg	28Aug2015	28Aug2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
12/1201	ND plus	07SEP2015	01DEC2015	Periradicular Infiltration S1 with Volon 40 mg	TRIAMCINOLONE	NASAL PREPARATIONS	Pain-study-rela ted	40 mg	28Aug2015	28Aug2015		
		07SEP2015	01DEC2015	Periradicular Infiltration S1 with Volon 40 mg	TRIAMCINOLONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-study-rela ted	40 mg	28Aug2015	28Aug2015		
		07SEP2015	01DEC2015	Periradicular Infiltration S1 with Volon 40 mg	TRIAMCINOLONE	OPHTHALMOLOGICA LS	Pain-study-rela ted	40 mg	28Aug2015	28Aug2015		
		07SEP2015	01DEC2015	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted	100 mg	22Aug2015	24Aug2015		
		07SEP2015	01DEC2015	Tilidin	/00628301/ VALORON N	ANALGESICS	Pain-study-rela ted	100 mg	07Sep2015	02Dec2015		
		07SEP2015	01DEC2015	Paracetamol	/00628301/ PARACETAMOL	ANALGESICS	Pain-study-rela ted	1000 mg	29Aug2015	11Sep2015		
		07SEP2015	01DEC2015	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 02)	1000 mg	01Dec2015	01Dec2015		AE-2
		07SEP2015	01DEC2015	Piritramid	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted (AE no. 02) mg	1 Ampulla 7.5	03Dec2015	05Dec2015		AE-2
		07SEP2015	01DEC2015	Diclac	DICLOFENAC	OPHTHALMOLOGICA LS	Pain-study-rela ted	150 mg	22Aug2015	28Aug2015		
		07SEP2015	01DEC2015	Diclac	DICLOFENAC	THROAT PREPARATIONS	Pain-study-rela ted	150 mg	22Aug2015	28Aug2015		
		07SEP2015	01DEC2015	Diclac	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted	150 mg	22Aug2015	28Aug2015		
		07SEP2015	01DEC2015	Diclac	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted	150 mg	22Aug2015	28Aug2015		
		07SEP2015	01DEC2015	Diclac	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	150 mg	22Aug2015	28Aug2015		
		07SEP2015	01DEC2015	Diclac	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	150 mg	22Aug2015	28Aug2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
12/1201	ND plus	07SEP2015	01DEC2015	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted	150 mg	25Aug2015	25Aug2015		
		07SEP2015	01DEC2015	Oxycodon	/00628301/ OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	30 mg	27Aug2015	28Aug2015		
		07SEP2015	01DEC2015	Piritramid	PIRITRAMIDE	ANALGESICS	Pain-study-rela ted	as necessary 7.5 mg	22Aug2015	07Sep2015		
		07SEP2015	01DEC2015	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 02)	1500 mg	02Dec2015	16Feb2016		AE-2
		07SEP2015	01DEC2015	Carbostetin	CARBOCISTEINE	COUGH AND COLD PREPARATIONS	Pain-study-rela ted	0.5 %/1 ml	28Sep2015	28Sep2015		
		07SEP2015	01DEC2015	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted	200 mg	26Aug2015	27Aug2015		
		07SEP2015	01DEC2015	Tilidin	/00628301/ VALORON N	ANALGESICS	Pain-study-rela ted (AE no. 02)	150 mg	03Dec2015	05Dec2015		AE-2
		07SEP2015	01DEC2015	Piritramid	/00628301/ PIRITRAMIDE	ANALGESICS	Pain-study-rela ted (AE no. 02)	1 ampule 7.5 mg	01Dec2015	01Dec2015		AE-2
		07SEP2015	01DEC2015	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 2 8 9)	500 mg	17Feb2016	30Aug2016		
		07SEP2015	01DEC2015	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted	200 mg	29Aug2015	06Sep2015		
		07SEP2015	01DEC2015	Novalgin (Metamizol)	/00628301/ METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	1500 mg	29Aug2015	11Sep2015		
		07SEP2015	01DEC2015	Novalgin (Metamizol)	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted	500 mg	12Sep2015	30Nov2015		
		07SEP2015	01DEC2015	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted (AE no. 02)	100 mg	06Dec2015	2016		AE-2
		07SEP2015	01DEC2015	Piritramid	/00628301/ PIRITRAMIDE	ANALGESICS	Pain-study-rela ted (AE no. 02)	2 ampule 15 mg	02Dec2015	02Dec2015		AE-2
13/1301	ND plus	27APR2015	29JUL2015	Targin 10/5 mg	TARGIN	ANALGESICS	Pain-study-rela ted	1 x d	17Apr2015	17Apr2015		
		27APR2015	29JUL2015	Targin 10/5 mg	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-study-rela ted	1 x d	17Apr2015	17Apr2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo ing? with MH/AE
13/1301	ND plus	27APR2015	29JUL2015	Oxygesic 5 mg accut	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	1-0-0	15Apr2015	16Apr2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1-1-1	26Apr2015	26Apr2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1-1-1	26Apr2015	26Apr2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1-1-1	26Apr2015	26Apr2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1-1-1	26Apr2015	26Apr2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1-1-1	26Apr2015	26Apr2015	
		27APR2015	29JUL2015	Oxygesic 5 mg	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	1-1-0	27Apr2015	28Apr2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	0-0-1	29Jul2015	29Jul2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	0-0-1	29Jul2015	29Jul2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	0-0-1	29Jul2015	29Jul2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	0-0-1	29Jul2015	29Jul2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	0-0-1	29Jul2015	29Jul2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1-1-1	13Apr2015	17Apr2015	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
13/1301	ND plus	27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1-1-1	13Apr2015	17Apr2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1-1-1	13Apr2015	17Apr2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1-1-1	13Apr2015	17Apr2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1-1-1	13Apr2015	17Apr2015	
		27APR2015	29JUL2015	Oxygesic 5 mg accut	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	1-1-1	12Apr2015	12Apr2015	
		27APR2015	29JUL2015	Valoron 100/8 mg	VALORON N	ANALGESICS	Pain-study-rela ted	0-0-1	17Apr2015	17Apr2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	/00628301/ CARDIAC THERAPY	Pain-study-rela ted	1-0-1	27Apr2015	27Apr2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1-0-1	27Apr2015	27Apr2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1-0-1	27Apr2015	27Apr2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1-0-1	27Apr2015	27Apr2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1-0-1	27Apr2015	27Apr2015	
		27APR2015	29JUL2015	Perfalgan 1 g	PARACETAMOL	ANALGESICS	Pain-study-rela ted	1x1 g	27Apr2015	28Apr2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1-1-1	30Jul2015	30Jul2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1-1-1	30Jul2015	30Jul2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1-1-1	30Jul2015	30Jul2015	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
13/1301	ND plus	27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1-1-1	30Jul2015	30Jul2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1-1-1	30Jul2015	30Jul2015	
		27APR2015	29JUL2015	Novalgin 500 mg	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela ted (AE no. 01 03)	1-1-1 on demand	22Mar2017	24Jun2020	
		27APR2015	29JUL2015	Pantoprazol 40 mg	PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Pain-study-rela ted	1 x d	13Apr2015	17Apr2015	
		27APR2015	29JUL2015	Oxygesic 5 mg accut	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	1 x d	13Apr2015	13Apr2015	
		27APR2015	29JUL2015	Valoron 100/8 mg	VALORON N	ANALGESICS	Pain-study-rela ted	1-0-1	18Apr2015	18Apr2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1-1-1	28Apr2015	04May2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1-1-1	28Apr2015	04May2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1-1-1	28Apr2015	04May2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1-1-1	28Apr2015	04May2015	
		27APR2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1-1-1	28Apr2015	04May2015	
		27APR2015	29JUL2015	Valoron 100/8 mg	VALORON N	ANALGESICS	Pain-study-rela ted	0-0-1	29Jul2015	29Jul2015	
		27APR2015	29JUL2015	Paracetamol 500 mg	PARACETAMOL	ANALGESICS	Pain-study-rela ted (AE no. 01 03)	up to 4x/d on demand	22Mar2017	24Jun2020	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
13/1301	ND plus	27APR2015	29JUL2015	Tagin 10/5 mg	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-study-rela 1-0-1 ted		13Apr2015	16Apr2015	
		27APR2015	29JUL2015	Tagin 10/5 mg	TARGIN	ANALGESICS	Pain-study-rela 1-0-1 ted		13Apr2015	16Apr2015	
		27APR2015	29JUL2015	Oxygesic 5 mg accut	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela 1-1-0 ted		14Apr2015	14Apr2015	
		27APR2015	29JUL2015	Tilidin 100/8 mg	VALORON N	ANALGESICS	Pain-study-rela 1-0-1 ted		26Apr2015	04May2015	
		27APR2015	29JUL2015	Pantoprazol 40 mg	/00628301/ PANTOPRAZOLE SODIUM SESQUIHYDRATE	DRUGS FOR ACID RELATED DISORDERS	Pain-study-rela 1 x d ted		26Apr2015	04May2015	
		27APR2015	29JUL2015	Valoron 100/8 mg	VALORON N	ANALGESICS	Pain-study-rela 1-0-1 ted		30Jul2015	30Jul2015	
		27APR2015	29JUL2015	Valoron 50/4	/00628301/ VALORON N	ANALGESICS	Pain-study-rela 1-1-1-0 ted (AE no. 01 03)		22Mar2017	23Mar2017	
13/1302	ND plus	12MAY2015	29JUL2015	Targin 20/10 mg	TARGIN	ANALGESICS	Pain-study-rela 1-0-1 ted		10May2015	12May2015	
		12MAY2015	29JUL2015	Targin 20/10 mg	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-study-rela 1-0-1 ted		10May2015	12May2015	
		12MAY2015	29JUL2015	Oxygesic 5 mg	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela 1-1-1 ted		06May2015	07May2015	
		12MAY2015	29JUL2015	Oxygesic 10 mg	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela 1-0-1 ted		10May2015	10May2015	
		12MAY2015	29JUL2015	Targin 10/5 mg	TARGIN	ANALGESICS	Pain-study-rela 0-0-1 ted		06May2015	06May2015	
		12MAY2015	29JUL2015	Targin 10/5 mg	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-study-rela 0-0-1 ted		06May2015	06May2015	
		12MAY2015	29JUL2015	Oxygesic 5 mg	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela 1-1-0 ted		08May2015	08May2015	
		12MAY2015	29JUL2015	Valoron 100/8 mg	VALORON N	ANALGESICS	Pain-study-rela 0-0-1 ted		29Jul2015	29Jul2015	
		12MAY2015	29JUL2015	Ibuprofen 600 mg	/00628301/ IBUPROFEN	CARDIAC THERAPY	Pain-study-rela 1-1-1 ted		30Jul2015	30Jul2015	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
13/1302	ND plus	12MAY2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1-1-1	30Jul2015	30Jul2015	
		12MAY2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1-1-1	30Jul2015	30Jul2015	
		12MAY2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1-1-1	30Jul2015	30Jul2015	
		12MAY2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1-1-1	30Jul2015	30Jul2015	
		12MAY2015	29JUL2015	Oxygesic 10 mg	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	1 x d	09May2015	09May2015	
		12MAY2015	29JUL2015	Targin 10/5 mg	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-study-rela ted	1-0-1	07May2015	09May2015	
		12MAY2015	29JUL2015	Targin 10/5 mg	TARGIN	ANALGESICS	Pain-study-rela ted	1-0-1	07May2015	09May2015	
		12MAY2015	29JUL2015	Oxygesic 5 mg	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	6 x 1	09May2015	09May2015	
		12MAY2015	29JUL2015	Oxygesic 10 mg	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	1-1-1	11May2015	11May2015	
		12MAY2015	29JUL2015	Valoron 100/8 mg	VALORON N	ANALGESICS	Pain-study-rela ted	1-0-1	30Jul2015	30Jul2015	
					/00628301/						
		12MAY2015	29JUL2015	Ibuprofen 600	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1-1-1	05May2015	16May2015	
		12MAY2015	29JUL2015	Ibuprofen 600	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1-1-1	05May2015	16May2015	
		12MAY2015	29JUL2015	Ibuprofen 600	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	1-1-1	05May2015	16May2015	
		12MAY2015	29JUL2015	Ibuprofen 600	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	1-1-1	05May2015	16May2015	
		12MAY2015	29JUL2015	Ibuprofen 600	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	1-1-1	05May2015	16May2015	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
13/1302	ND plus	12MAY2015	29JUL2015	Targin 10/5 mg	TARGIN	ANALGESICS	Pain-study-rela ted	1-0-0	10May2015	10May2015	
		12MAY2015	29JUL2015	Targin 10/5 mg	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-study-rela ted	1-0-0	10May2015	10May2015	
		12MAY2015	29JUL2015	Oxygesic 10 mg	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela ted	1-0-0	12May2015	12May2015	
		12MAY2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	0-0-1	29Jul2015	29Jul2015	
		12MAY2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	0-0-1	29Jul2015	29Jul2015	
		12MAY2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	0-0-1	29Jul2015	29Jul2015	
		12MAY2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	0-0-1	29Jul2015	29Jul2015	
		12MAY2015	29JUL2015	Ibuprofen 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	0-0-1	29Jul2015	29Jul2015	
13/1303	SC	29JUN2015	-	Diclofenac	DICLOFENAC	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted (AE no. 02)	75 mg	04Dec2017	04Dec2017	AE-2
		29JUN2015	-	Diclofenac	DICLOFENAC	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted (AE no. 02)	75 mg	04Dec2017	04Dec2017	AE-2
		29JUN2015	-	Diclofenac	DICLOFENAC	OTHER DERMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 02)	75 mg	04Dec2017	04Dec2017	AE-2
		29JUN2015	-	Diclofenac	DICLOFENAC	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 02)	75 mg	04Dec2017	04Dec2017	AE-2
		29JUN2015	-	Diclofenac	DICLOFENAC	THROAT PREPARATIONS	Pain-study-rela ted (AE no. 02)	75 mg	04Dec2017	04Dec2017	AE-2
		29JUN2015	-	Diclofenac	DICLOFENAC	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 02)	75 mg	04Dec2017	04Dec2017	AE-2

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
13/1303	SC	29JUN2015	-	Ibuprofen	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	600 mg, 3 x d	24Jun2015	03Jul2015		
		29JUN2015	-	Ibuprofen	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	600 mg, 3 x d	24Jun2015	03Jul2015		
		29JUN2015	-	Ibuprofen	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	600 mg, 3 x d	24Jun2015	03Jul2015		
		29JUN2015	-	Ibuprofen	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	600 mg, 3 x d	24Jun2015	03Jul2015		
		29JUN2015	-	Ibuprofen	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	600 mg, 3 x d	24Jun2015	03Jul2015		
		29JUN2015	-	Tilidin 50/4 mg	VALORON N	ANALGESICS	Pain-study-rela ted	0-0-1	02Jul2015	02Jul2015		
		29JUN2015	-	Dexameteson	DEXAMETHASONE	OPHTHALMOLOGICA LS	Pain-study-rela ted (AE no. 02)	4 mg	04Dec2017	04Dec2017		AE-2
		29JUN2015	-	Dexameteson	DEXAMETHASONE	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	Pain-study-rela ted (AE no. 02)	4 mg	04Dec2017	04Dec2017		AE-2
		29JUN2015	-	Dexameteson	DEXAMETHASONE	OTOLOGICALS	Pain-study-rela ted (AE no. 02)	4 mg	04Dec2017	04Dec2017		AE-2
		29JUN2015	-	Dexameteson	DEXAMETHASONE	OTHER RESPIRATORY SYSTEM PRODUCTS	Pain-study-rela ted (AE no. 02)	4 mg	04Dec2017	04Dec2017		AE-2
		29JUN2015	-	Dexameteson	DEXAMETHASONE	NASAL PREPARATIONS	Pain-study-rela ted (AE no. 02)	4 mg	04Dec2017	04Dec2017		AE-2
		29JUN2015	-	Dexameteson	DEXAMETHASONE	STOMATOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 02)	4 mg	04Dec2017	04Dec2017		AE-2
		29JUN2015	-	Dexameteson	DEXAMETHASONE	VASOPROTECTIVES	Pain-study-rela ted (AE no. 02)	4 mg	04Dec2017	04Dec2017		AE-2
		29JUN2015	-	Dexameteson	DEXAMETHASONE	OPHTHALMOLOGICA L AND OTOLOGICAL PREPARATIONS	Pain-study-rela ted (AE no. 02)	4 mg	04Dec2017	04Dec2017		AE-2

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
13/1303	SC	29JUN2015	-	Dexameteson	DEXAMETHASONE	CORTICOSTEROIDS	Pain-study-rela ted (AE no. 02)	4 mg	04Dec2017	04Dec2017		AE-2
		29JUN2015	-	Dexameteson	DEXAMETHASONE	ANTI-ACNE PREPARATIONS	Pain-study-rela ted (AE no. 02)	4 mg	04Dec2017	04Dec2017		AE-2
		29JUN2015	-	Dexameteson	DEXAMETHASONE	CORTICOSTEROIDS FOR SYSTEMIC USE	Pain-study-rela ted (AE no. 02)	4 mg	04Dec2017	04Dec2017		AE-2
		29JUN2015	-	Ibuhexal	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	600 mg	23Jun2015	23Jun2015		
		29JUN2015	-	Ibuhexal	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	600 mg	23Jun2015	23Jun2015		
		29JUN2015	-	Ibuhexal	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela ted	600 mg	23Jun2015	23Jun2015		
		29JUN2015	-	Ibuhexal	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela ted	600 mg	23Jun2015	23Jun2015		
		29JUN2015	-	Ibuhexal	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela ted	600 mg	23Jun2015	23Jun2015		
		29JUN2015	-	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted	100/8 mg, 1-0-1	30Jun2015	01Jul2015		
		29JUN2015	-	Tilidin 50/4 mg	/00628301/ VALORON N	ANALGESICS	Pain-study-rela ted	1-0-1	03Jul2015	03Jul2015		
		29JUN2015	-	Ortoton 750 mg	/00628301/ METHOCARBAMOL	MUSCLE RELAXANTS	Pain-study-rela ted (AE no. 02)	2-2-2	04Dec2017	09Dec2017		AE-2
		29JUN2015	-	Tilidin	VALORON N	ANALGESICS	Pain-study-rela ted	100/8 mg, 1-0-0	02Jul2015	02Jul2015		
13/1304	ND basic	02JUL2015	18SEP2015	Ibuprofen 600 mg	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela ted	1/1/1	22Jun2015	09Jul2015		
		02JUL2015	18SEP2015	Ibuprofen 600 mg	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela ted	1/1/1	22Jun2015	09Jul2015		

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Assoc iated Ongo with ing? MH/AE
13/1304	ND basic	02JUL2015	18SEP2015	Ibuprofen 600 mg	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela 1/1/1 ted	1/1/1	22Jun2015	09Jul2015	
		02JUL2015	18SEP2015	Ibuprofen 600 mg	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela 1/1/1 ted	1/1/1	22Jun2015	09Jul2015	
		02JUL2015	18SEP2015	Ibuprofen 600 mg	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela 1/1/1 ted	1/1/1	22Jun2015	09Jul2015	
		02JUL2015	18SEP2015	Targin 10/5 mg	TARGIN	OTHER NERVOUS SYSTEM DRUGS	Pain-study-rela 1-0-1 ted	1-0-1	22Jun2015	23Jun2015	
		02JUL2015	18SEP2015	Targin 10/5 mg	TARGIN	ANALGESICS	Pain-study-rela 1-0-1 ted	1-0-1	22Jun2015	23Jun2015	
		02JUL2015	18SEP2015	Ibuprofen 600	IBUPROFEN	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-rela 1-1-1 ted (AE no. 02)	1-1-1	Mar2018	24Mar2018	AE-2
		02JUL2015	18SEP2015	Ibuprofen 600	IBUPROFEN	ANTIINFLAMMATOR Y AND ANTIRHEUMATIC PRODUCTS	Pain-study-rela 1-1-1 ted (AE no. 02)	1-1-1	Mar2018	24Mar2018	AE-2
		02JUL2015	18SEP2015	Ibuprofen 600	IBUPROFEN	OTHER GYNECOLOGICALS	Pain-study-rela 1-1-1 ted (AE no. 02)	1-1-1	Mar2018	24Mar2018	AE-2
		02JUL2015	18SEP2015	Ibuprofen 600	IBUPROFEN	THROAT PREPARATIONS	Pain-study-rela 1-1-1 ted (AE no. 02)	1-1-1	Mar2018	24Mar2018	AE-2
		02JUL2015	18SEP2015	Ibuprofen 600	IBUPROFEN	CARDIAC THERAPY	Pain-study-rela 1-1-1 ted (AE no. 02)	1-1-1	Mar2018	24Mar2018	AE-2
		02JUL2015	18SEP2015	Valoron 100/8 mg	VALORON N	ANALGESICS	Pain-study-rela 1/0/1 ted	1/0/1	01Jul2015	09Jul2015	
		02JUL2015	18SEP2015	Novalgin gtt (Metamizol)	/00628301/ METAMIZOLE SODIUM		Pain-study-rela 4x30 gtt ted	4x30 gtt	21Jun2015	24Jun2015	
		02JUL2015	18SEP2015	Paracetamol	PARACETAMOL	ANALGESICS	Pain-study-rela 1 x 1 g ted	1 x 1 g	21Jun2015	21Jun2015	
		02JUL2015	18SEP2015	Novalgin 500 mg	METAMIZOLE SODIUM	ANALGESICS	Pain-study-rela 2-2-2-2 ted (AE no. 02)	2-2-2-2	Mar2018	24Mar2018	AE-2
		02JUL2015	18SEP2015	Oxygesic accut 5 mg	OXYCODONE HYDROCHLORIDE	ANALGESICS	Pain-study-rela 1 x d ted	1 x d	21Jun2015	22Jun2015	

Listing 16.2.1.12: Previous and concomitant pain medication - all enrolled subjects

Site/ SubjectID	Treatment group	Date of sequestre ctomy	Date of transplant /implant	Reported name	Standardized medication name	Medication class	Indication	Daily Dose	Start Date	Stop Date	Ongo ing?	Assoc iated with MH/AE
13/1304	ND basic	02JUL2015	18SEP2015	Tilidin	VALORON N	ANALGESICS	Pain-study-related (AE no. 02)	as needed	Mar2018	24Mar2018		AE-2
		02JUL2015	18SEP2015	Voltaren res.	/00628301/ DICLOFENAC RESINATE	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	Pain-study-related	75mg - 0 - 75mg	21Jun2015	22Jun2015		
		02JUL2015	18SEP2015	Voltaren res.	DICLOFENAC RESINATE	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	Pain-study-related	75mg - 0 - 75mg	21Jun2015	22Jun2015		
		02JUL2015	18SEP2015	Voltaren res.	DICLOFENAC RESINATE	OPHTHALMOLOGICALS	Pain-study-related	75mg - 0 - 75mg	21Jun2015	22Jun2015		

Listing 16.2.1.13: Previous and concomitant non-drug therapies - all enrolled subjects

Site/ SubjectID	Treatment group	Spinal Therapy	Start Date	End Date	Ongoing?
01/0103	ND basic	Physiotherapy	Mar2013	Apr2013	
	ND basic	Physiotherapy (for Shoulder)	Oct2013	Nov2013	
	ND basic	Physiotherapy	Nov2017	Nov2017	
01/0104	ND basic	Physiotherapy	Aug2012	Sep2012	
	ND basic	Physiotherapy	Aug2013	Sep2013	
	ND basic	Dry Needling Therapy	Aug2016	Sep2016	
	ND basic	Physiotherapy	Oct2012	Jan2013	
	ND basic	Osteopathic treatment	Sep2012	Dec2012	
	ND basic	Physiotherapy 9 E	Jul2013	Sep2013	
01/0107	ND plus	Physiotherapy	Jan2013	Jan2013	
	ND plus	PHYSIOTHERAPY	Jul2014	Dec2014	
	ND plus	Physiotherapy	Feb2013	Mar2013	
01/0108	ND plus	Physiotherapy 2 X	Dec2012	Jan2013	
	ND plus	PHYSIOTHERAPY	Jul2014	Dec2014	
	ND plus	Physiotherapy	Mar2017		Yes
01/0110	ND basic	Physiotherapy 9 X	May2012	Oct2012	
	ND basic	MASSAGE 10E	Mar2014	May2014	
	ND basic	Physiotherapy 3 X	Apr2013	Apr2013	
	ND basic	Muscle electrostimulation	Jan2013	Jan2013	
	ND basic	Physiotherapy	May2013	Dec2013	
	ND basic	Physiotherapy 4 X	Apr2013	May2013	
01/0111	ND plus	Physiotherapy 18 E	May2013	May2013	
01/0112	ND basic	Physiotherapy	Sep2012	Oct2012	
	ND basic	Physiotherapy	Feb2013	Feb2013	
	ND basic	Physiotherapy	May2013	Jun2013	
01/0113	ND basic	back and ventral training	2008		Yes
01/0114	ND basic	Accupunktur	Jun2013	Jun2013	
	ND basic	PHYSIOTHERAPY 12E	Oct2013	Dec2013	
	ND basic	Osteopathic treatment	Aug2013	Aug2013	
	ND basic	Osteopathic treatment monthly	Oct2013		Yes
	ND basic	Muscle electrostimulation	Jun2013	Aug2013	
01/0115	ND plus	back care education	Nov2012	Dec2012	

Listing 16.2.1.13: Previous and concomitant non-drug therapies - all enrolled subjects

Site/ SubjectID	Treatment group	Spinal Therapy	Start Date	End Date	Ongoing?
01/0115	ND plus ND plus	rehab back massage/fango	Jan2015 Feb2013	Jan2015 Apr2013	
01/0116	ND basic	Physiotherapy 10 E	Feb2013	May2013	
01/0118	ND plus ND plus ND plus ND plus	Physiotherapy R SPINAL REHAB Massage Physiotherapy	Jun2013 Sep2016 Jun2013 Dec2013	Jul2013 Sep2016 Jul2013 Dec2013	
01/0119	ND basic ND basic ND basic	PHYSIO 36E (THERAPY) PHYSIOTHERAPY (+STRENGTH TRAINING) PHYSIOTHERAPY	2012 Nov2013 Sep2013	Jun2013 Dec2013 Oct2013	
01/0121	ND plus	Physiotherapy	Aug2013	Sep2013	
01/0122	ND plus ND plus ND plus	PHYSIOTHERAPY 8E PHYSIOTHERAPY PHYSIOTHERAPY	May2014 Nov2016 Nov2017	Jun2014 Nov2016 Dec2017	
01/0123	ND plus ND plus ND plus ND plus ND plus ND plus ND plus ND plus ND plus ND plus ND plus	PHYSIOTHERAPY (some dates) PHYSIOTHERAPY 8E PHYSIOTHERAPY 8E PHYSIOTHERAPY 8E PHYSIOTHERAPY 8E MASSAGE 8E MASSAGE (some dates) MASSAGE 8E Physiotherapy Massage	Jan2014 May2018 Nov2014 Jul2018 Feb2015 May2018 Jan2014 Jul2018 Oct2018 Oct2018	Mar2014 Jun2018 Dec2014 Aug2018 Mar2015 Jun2018 Mar2014 Aug2018 Dec2018 Dec2018	
01/0124	ND plus ND plus	PHYSIOTHERAPY PHYSIOTHERAPY	May2014 Oct2014	Sep2014 Oct2014	
01/0125	SC SC	PHYSIOTHERAPY PHYSIOTHERAPY	Nov2014 Feb2019	Jun2019	Yes
01/0126	ND basic ND basic	PHYSIOTHERAPY PHYSIOTHERAPY	Nov2014 Jun2015	Feb2015 Jan2016	
01/0127	ND plus	PHYSIOTHERAPY	May2014	Jul2014	

Listing 16.2.1.13: Previous and concomitant non-drug therapies - all enrolled subjects

Site/ SubjectID	Treatment group	Spinal Therapy	Start Date	End Date	Ongoing?
01/0127	ND plus	PHYSIOTHERAPIE	Oct2016	Dec2016	Yes
	ND plus	PHYSIOTHERAPY	Mar2017	Apr2017	
	ND plus	PHYSIOTHERAPY	Dec2014	Mar2015	
	ND plus	PHYSIOTHERAPY	Sep2017	Dec2017	
	ND plus	PHYSIOTHERAPY	Apr2015	May2015	
	ND plus	PHYSIOTHERAPY	Feb2018		
01/0128	ND plus	PHYSIOTHERAPY	Sep2014	Oct2014	
	ND plus	PHYSIOTHERAPY	Jan2017	Mar2017	
	ND plus	PHYSIOTHERAPY	Jan2017	Aug2017	
	ND plus	ERGOTHERAPY 12E	Jan2015	Apr2015	
	ND plus	PHYSIOTHERAPY	Dec2014	Jan2015	
01/0129	SC	PHYSIOTHERAPY	Nov2014	Dec2014	
	SC	OSTEOPATHIC TREATMENT	May2016	May2016	
	SC	MASSAGE	Mar2018	Mar2018	
	SC	MUSCLE ELECTROSTIMULATION	Nov2014	Dec2014	
	SC	OSTEOPATHIC TREATMENT (FOR BONE DISORDER)	Sep2018	Sep2018	
	SC	REHAB 21 d	Feb2015	Mar2015	
	SC	PHYSIOTHERAPY	May2019	Jun2019	
	SC	OSTEOPATHIC TREATMENT	Sep2015	Oct2015	
	SC	PHYSIOTHERAPY	Mar2018	Mar2018	
	SC	PHYSIOTHERAPY	May2015	UNK	
01/0131	ND plus	Physiotherapy	Mar2015	Apr2015	
	ND plus	PHYSIOTHERAPY	Jan2019	Feb2019	
	ND plus	CURE TREATMENT (REHAB)	Nov2015	Dec2015	
	ND plus	Rehabilitation	Mar2019	Mar2019	
01/0132	SC	PHYSIOTHERAPY 8E	Nov2014	Nov2014	
	SC	Physiotherapy	May2017	2017	
	SC	LASERTHERAPY 8E	Nov2014	Nov2014	
	SC	Physiotherapy	Jan2019	Jan2019	
	SC	MUSCLE ELECTROSTIMULATION	Nov2014	Nov2014	
	SC	REHAB 21 d	Jan2015	Feb2015	
01/0134	ND basic	Muscle electrostimulation	Nov2014	Dec2014	
01/0135	ND plus	PHYSIOTHERAPY	Mar2015	Apr2015	
	ND plus	PHYSIOTHERAPY	Apr2019	May2019	

Listing 16.2.1.13: Previous and concomitant non-drug therapies - all enrolled subjects

Site/ SubjectID	Treatment group	Spinal Therapy	Start Date	End Date	Ongoing?
01/0135	ND plus	Physiotherapy	Oct2018	Oct2018	
01/0136	ND basic	PHYSIOTHERAPY	Dec2014	Jan2015	
	ND basic	Peripheral nerve neurostimulation / TENS=transcutaneous electrical nerve stimulation	Dec2016	Jan2019	
	ND basic	PHYSIOTHERAPY	Mar2015	May2015	
01/0137	ND plus	PHYSIOTHERAPY	Aug2015	Oct2015	
	ND plus	curative massage	2015	Oct2015	
01/0138	SC	PHYSIOTHERAPY	Jan2015	Mar2015	
	SC	Physiotherapy	Jan2017	Mar2017	
	SC	PHYSIOTHERAPY	Mar2015	May2015	
01/0139	ND plus	PHYSIOTHERAPY	Feb2015	Mar2015	
	ND plus	Physiotherapy	Jan2017		Yes
	ND plus	PHYSIOTHERAPY	Apr2015	May2015	
	ND plus	INFRARED THERAPY	Feb2015	Mar2015	
01/0140	ND basic	PHYSIOTHERAPY	Jun2015	Jul2015	
	ND basic	PHYSIOTHERAPY	Sep2015	Oct2015	
01/0141	SC	PHYSIOTHERAPY	May2015	May2015	
	SC	Physiotherapy	Dec2018	Feb2019	
	SC	REHAB	Aug2015	Aug2015	
	SC	MUSCLE STRENGTH TRAINING	Sep2015		Yes
01/0142	ND plus	PHYSIOTHERAPY 8E	Apr2015	May2015	
	ND plus	PHYSIOTHERAPY	Sep2015	Aug2017	
	ND plus	PHYSIOTHERAPY	Feb2019	Mar2019	
	ND plus	PHYSIOTHERAPY 8E	Jul2015	Aug2015	
	ND plus	PHYSIOTHERAPY 8E	Aug2015	Sep2015	
01/0143	ND plus	PHYSIOTHERAPY	Dec2015		Yes
	ND plus	SPINAL REHAB	May2016	May2016	
01/0144	ND basic	PHYSIOTHERAPY	Aug2015	Oct2015	
	ND basic	PHYSIOTHERAPY	Mar2019	Apr2019	
	ND basic	PHYSIOTHERAPY	Nov2015	Dec2015	
	ND basic	NERVE ROOT INFILTRATION	May2019	May2019	

Listing 16.2.1.13: Previous and concomitant non-drug therapies - all enrolled subjects

Site/ SubjectID	Treatment group	Spinal Therapy	Start Date	End Date	Ongoing?
01/0145	ND plus	PHYSIOTHERAPY	Aug2015	Sep2015	
01/0146	SC	REHAB	Sep2015	Sep2015	
01/0147	ND plus	PHYSIOTHERAPY	Jul2015	Jul2015	
	ND plus	PHYSIOTHERAPY	May2019	Jun2019	
	ND plus	Osteopathy (Therapy)	Apr2020	Sep2020	
	ND plus	MUSCLE ELECTROSTIMULATION	Jul2015	Jul2015	
01/0148	ND plus	PHYSIOTHERAPY	Aug2015	Oct2015	
	ND plus	Physiotherapy	Oct2016		Yes
	ND plus	CURE VACATION	Oct2019	Nov2019	
	ND plus	PHYSIOTHERAPY	Dec2015	May2016	
01/0149	ND plus	PHYSIOTHERAPY	Oct2015	Nov2015	
	ND plus	Physiotherapy / Massages	Nov2017	Dec2017	
01/0151	ND basic	PHYSIOTHERAPY	Apr2016	May2016	
01/0152	SC	PHYSIOTHERAPY	May2016	Jul2016	
	SC	Physiotherapy	Jan2018	Feb2018	
	SC	Physiotherapy	Jul2019	Aug2019	
	SC	Physiotherapy	Dec2019	Jan2020	
01/0153	ND basic	PHYSIO	Sep2016	Oct2016	
	ND basic	PHYSIOTHERAPY	Dec2018	Feb2019	
	ND basic	Physiotherapy	Jul2020	Nov2020	
	ND basic	MASSAGE	Dec2018	Feb2019	
02/0201	ND plus	Physiotherapy/Rehab	Mar2013	Apr2013	
02/0202	ND basic	Physiotherapy	Apr2013	Apr2013	
02/0203	ND basic	Physiotherapy	Mar2013	Mar2013	
	ND basic	Outpatient rehabilitation	Apr2013	May2013	
	ND basic	manual Therapy	Feb2014	Feb2016	
	ND basic	manual Therapy	Mar2016	Mar2016	
	ND basic	Physiotherapie	Mar2016		Yes
02/0204	ND basic	Physiotherapy	Apr2013	Mar2013	

Listing 16.2.1.13: Previous and concomitant non-drug therapies - all enrolled subjects

Site/ SubjectID	Treatment group	Spinal Therapy	Start Date	End Date	Ongoing?
02/0205	ND basic	Physiotherapy	May2013	May2013	
02/0206	ND plus	Physiotherapy	Aug2013	Sep2013	
02/0207		Physiotherapy Rehabilitation	UN UN	UN UN	
02/0208	ND plus	In-patient rehabilitation	Sep2013	Oct2013	
02/0209	ND plus ND plus ND plus	Physiotherapy Physiotherapy Rehabilitation	Oct2014 Nov2014 Nov2014	Oct2014 Dec2014 Dec2014	
02/0210		Physiotherapy	Sep2014	Nov2014	
02/0211	ND basic	Reha	Jan2015	Jan2015	
02/0212	SC	Physiotherapy	Jan2015	Feb2015	
02/0214	ND plus	Rehabilitation	Dec2014	Jan2015	
02/0219	ND basic ND basic	Physiotherapy Rehabilitation	Jan2015 Jun2015	Jun2015 Jul2015	
02/0220	SC SC	Rehabilitation IRENA Rehabilitation	Aug2015 Sep2015	Sep2015 Dec2015	
02/0221	ND plus	Physiotherapy	Oct2015	Dec2015	
02/0223	ND basic	Reha Bad Lausich	Jan2016	Feb2016	
04/0401	SC SC SC	periradicular infiltration periradicular infiltration physiotherapy	Jun2015 May2015 Jan2015	Jun2015 May2015 Feb2015	
06/0602	ND plus	Physiotherapy	Jul2013	Sep2013	
06/0606	SC SC SC	physiotherapy Red light therapy acupuncture	Mar2015 Sep2016 Jun2015	Mar2015 Sep2016 Sep2015	

Listing 16.2.1.13: Previous and concomitant non-drug therapies - all enrolled subjects

Site/ SubjectID	Treatment group	Spinal Therapy	Start Date	End Date	Ongoing?
06/0608	SC	Pain therapy	Jan2015		Yes
06/0610	ND plus	Rehabilitation	Jul2015	Aug2015	
	ND plus	Physiotherapy	Aug2015	UNK	
	ND plus	Rehabilitation	Feb2016	Mar2016	
06/0612	ND plus	Rehabilitation	Aug2015	Sep2015	
	ND plus	Physiotherapy	Jul2015	Aug2015	
	ND plus	Physiotherapy	Sep2015	Nov2015	
	ND plus	Physiotherapy	Dec2015	Dec2016	
06/0613	SC	Rehabilitation	Aug2015	Sep2015	
	SC	Physiotherapy	Sep2015	Oct2015	
06/0614	ND plus	Rehabilitation	Sep2015	Sep2015	
	ND plus	Physiotherapy	Nov2015	Jan2016	
	ND plus	Physiotherapy	Apr2016	Jul2016	
	ND plus	Rehabilitation	Sep2016	Oct2016	
06/0617	ND plus	Rehabilitation	Jan2016	Feb2016	
06/0619	ND basic	Rehabilitation	Mar2016	Apr2016	
	ND basic	Physiotherapy	Sep2017	Oct2017	
	ND basic	Physiotherapy	Apr2016	Apr2016	
06/0620	SC	Rehabilitation	Mar2016	Mar2016	
	SC	Physiotherapy	Sep2020		Yes
	SC	Physiotherapy	Apr2016	Apr2016	
07/0701	ND plus	Physiotherapy (10 Session)	Apr2015	Jul2015	
07/0702	SC	Physiotherapy	Feb2015	Apr2015	
07/0703	ND plus	Physio	Apr2015	May2015	
	ND plus	Rehab sports (1x/w)	Jun2016	Aug2015	
07/0707		Physiotherapy	Jan2016		Yes
08/0801	SC	Rehabilitation	Nov2014	Dec2014	
	SC	Physiotherapy	Jan2015	Apr2015	
	SC	Physical Therapy	Jan2015		Yes

Listing 16.2.1.13: Previous and concomitant non-drug therapies - all enrolled subjects

Site/ SubjectID	Treatment group	Spinal Therapy	Start Date	End Date	Ongoing?
08/0801	SC	Physiotherapy	Jan2015	Apr2015	
08/0802	ND plus	Physiotherapy (cervical)	Dec2016	Jan2017	
	ND plus	Physiotherapy (lumbar)	Jan2015	Feb2015	
	ND plus	Physiotherapy (cervical)	2017	2018	
	ND plus	+ Massage (cervical)	Dec2016	Jan2017	
	ND plus	Physiotherapy (lumbar)	Aug2015	Aug2015	
	ND plus	Massage (spine)	2017	2018	
	ND plus	Physiotherapy (cervical)	Dec2015		Yes
	ND plus	Physiotherapy (cervical)	Jul2018	Oct2018	
	ND plus	Massage	Jul2018	Oct2018	
	ND plus	Physiotherapy (cervical)	Nov2018	Dec2018	
08/0803	ND basic	Physiotherapy	Feb2015	Mar2015	
	ND basic	Physiotherapy	Jun2015	Jul2015	
08/0804	ND plus	Physiotherapy	Sep2015	Oct2015	
08/0805	ND basic	Physiotherapy	Apr2015	May2015	
	ND basic	physiotherapy	Jun2015	Sep2015	
	ND basic	physiotherapy	Jul2016	Aug2016	
	ND basic	Physiotherapy	Nov2016	Dec2016	
	ND basic	physiotherapy	Jul2018		Yes
	ND basic	physiotherapy	Oct2015	Dec2015	
08/0806	ND plus	physiotherapy	Jul2015	Sep2015	
	ND plus	physiotherapy	2019		Yes
08/0807	ND plus	physiotherapy, rehabilitation	Dec2015	Dec2015	
	ND plus	physiotherapy	Jan2018	Feb2018	
	ND plus	Physiotherapy	Jan2016	Feb2016	
	ND plus	Massage	Apr2016	Apr2016	
	ND plus	Manual therapy	Apr2016	Apr2016	
08/0808	SC	Physiotherapy (post-surgery)	Dec2015	Dec2015	
	SC	Massage	Sep2016	Sep2016	
	SC	Acupuncture	Mar2017	Apr2017	
	SC	physiotherapy	Feb2016	Mar2016	
	SC	physiotherapy rehabilitation	Jan2016	Jan2016	
	SC	accupuncture	Jun2018	Jun2018	
	SC	Acupuncture	Apr2016	Apr2016	

Listing 16.2.1.13: Previous and concomitant non-drug therapies - all enrolled subjects

Site/ SubjectID	Treatment group	Spinal Therapy	Start Date	End Date	Ongoing?
08/0808	SC	massage	Jun2018	Jun2018	
09/0901	SC	Physiotherapy	Nov2014	Apr2015	
	SC	Rootblock S1 re	Dec2014	Dec2014	
	SC	Physiotherapy with manuel therapy	Dec2014	Apr2015	
	SC	Swimming	Dec2014		Yes
	SC	Ergometer workouts	Dec2014		Yes
	SC	Osteopathic treatment	Apr2015	May2015	
	SC	Osteopathic treatment	Jun2015	Jul2015	
09/0903	ND plus	periradikular infiltration	Oct2014	Nov2014	
	ND plus	Med. rehabilitation treatment	Jan2015	Jan2015	
09/0904	ND basic	Physiotherapy	Jul2015	Nov2015	
	ND basic	Physiotherapy	Nov2015	May2016	
09/0905	ND plus	Rehab measure	Nov2015	Nov2015	
	ND plus	Outpatient rehab (Terena)	Jun2019	Mar2020	
	ND plus	Physiotherapy	Dec2015	Mar2016	
09/0907	SC	KG Physiotherapy	Nov2014	Dec2014	
	SC	KG Physiotherapy	May2015	UNK	
09/0908	ND basic	Physiotherapie	Mar2015	Apr2015	
09/0909	ND plus	Physiotherapy	May2015	May2015	
	ND plus	periradicular inj. S1 left	May2015	May2015	
	ND plus	Physiotherapy 2x week	Jul2015	Jul2015	
	ND plus	Physiotherapy 1x week	Aug2015	Aug2015	
	ND plus	Physiotherapy 1x week	Sep2015	Oct2015	
	ND plus	Rehab sport 1x week	Nov2015	Dec2015	
	ND plus	Rehab sport 2x week	Jan2016	Jun2016	
09/0910	ND plus	periradicular Injection	Aug2015	Aug2015	
09/0911	ND plus	Physiotherapy	Apr2015	Apr2015	
	ND plus	Outpatient rehab	Nov2015	Dec2015	
09/0912	ND plus	Physiotherapy	Sep2015	Oct2015	
	ND plus	Inpatient rehabilitation	Dec2015	Dec2015	
	ND plus	Physiotherapy	Jan2016	Jan2016	

Listing 16.2.1.13: Previous and concomitant non-drug therapies - all enrolled subjects

Site/ SubjectID	Treatment group	Spinal Therapy	Start Date	End Date	Ongoing?
09/0912	ND plus	Physiotherapy	Feb2016	Feb2016	
	ND plus	Physiotherapy	Mar2016	Apr2016	
09/0913	ND basic	Physiotherapy	Jan2016	Feb2016	
09/0914	SC	Outpatient rehab	Mar2016	Apr2016	
	SC	IRENA Prog. Physiotherapy	May2016		Yes
09/0915	ND basic	Physiotherapy on apparatus	Feb2016		Yes
	ND basic	Massage	Dec2016	Jan2017	
	ND basic	Physiotherapie	Jul2020	Jul2020	
09/0916	SC	Outpatient rehabilitation	Apr2016	Apr2016	
10/1001		Physiotherapy	Sep2015	Sep2015	
		Physiotherapy	Nov2015	Nov2015	
11/1101	ND plus	Physiotherapy (1x/week)	Apr2015	Aug2015	
	ND plus	physiotherapy	Jan2017	Apr2017	
	ND plus	Physiotherapy	Nov2017		Yes
	ND plus	Rehab-sport (1x week)	Apr2015	Jan2017	
	ND plus	rehabilitation	May2017	Jul2017	
11/1102	ND basic	Manual therapy, 6 x 30 min	Mar2015	Mar2015	
	ND basic	Manual therapy, 6 x 30 min	Jun2015	Jun2015	
	ND basic	Physiotherapy devices 4 x 60 min	Jun2015	Jul2015	
11/1103	SC	massage if back complaints	Jun2015	Jul2015	
	SC	watergym once per week	Feb2017		Yes
	SC	Rehabilitation	Aug2015	Sep2015	
11/1104	ND plus	Rehabilitation	Apr2016	May2016	
	ND plus	rehabilitation "Irena-therapy"	Jul2016	Nov2016	
	ND plus	physiotherapy once a week	May2017		Yes
12/1201	ND plus	Physiotherapy	Sep2015	Sep2015	
	ND plus	Thermodenervation	Jul2017	Jul2017	
	ND plus	ISG Denervation	Dec2018	Dec2018	
	ND plus	mud pack	Sep2015	Sep2015	
	ND plus	Psychologie rehabilitation	Apr2017	May2017	
	ND plus	Thermodenervation ISG right	Dec2018	Dec2018	

Listing 16.2.1.13: Previous and concomitant non-drug therapies - all enrolled subjects

Site/ SubjectID	Treatment group	Spinal Therapy	Start Date	End Date	Ongoing?
12/1201	ND plus	Thermodenervation 2 WK right	Dec2018	Dec2018	
	ND plus	Thermodenervation ISG left	Jan2019	Jan2019	
	ND plus	Thermodenervation 2 WK left	Jan2019	Jan2019	
	ND plus	Radiotherapy 0.5 Gy	Sep2019	Sep2019	
	ND plus	Radiotherapy 0.5 Gy	Jan2020	Jan2020	
13/1301	ND plus	PHYSIOTHERAPIE	Apr2015	Jun2015	
	ND plus	Physiotherapy	Mar2017	Jun2020	
13/1304	ND basic	physiotherapy	Jul2015	Sep2015	
	ND basic	physiotherapy	Jul2016		Yes
	ND basic	Physiotherapy	Apr2018	May2018	
	ND basic	rehabilitation (IRENA)	Nov2015	Nov2015	
	ND basic	physiotherapy	Jul2016		Yes

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
01/0103	ND basic	BASELINE (VISIT 2A)	4	2	3	0	1	4	2	4	0	0	40.00
	ND basic	VISIT 3A	3	1	2	1	2	1	1	1	2	1	30.00
	ND basic	VISIT 4	3	2	2	1	3	1	3	4	2	1	44.00
	ND basic	VISIT 5	4	2	4	2	2	1	3	1	2	2	46.00
	ND basic	VISIT 6	2	2	1	1	2	2	2	1	3	3	38.00
	ND basic	VISIT 7	3	2	2	0	2	1	2	2	2	1	34.00
	ND basic	VISIT 8	4	3	4	2	2	1	2	3	1	3	50.00
	ND basic	VISIT 9	4	3	4	2	2	3	3	4	3	3	62.00
	ND basic	VISIT 10	2	2	2	2	2	1	2	2	3	3	42.00
	ND basic	VISIT 11	3	3	2	2	2	2	3	1	3	3	48.00
01/0104	ND basic	BASELINE (VISIT 2A)	3	1	3	2	2	2	0	3	1	1	36.00
	ND basic	VISIT 3A	0	0	0	0	1	0	0	0	0	0	2.00
	ND basic	VISIT 4	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 5	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 6	2	1	1	1	2	1	1	0	0	1	20.00
	ND basic	VISIT 7	1	0	1	0	1	1	0	0	0	1	10.00
	ND basic	VISIT 8	0	0	0	0	1	1	0	0	0	0	4.00
	ND basic	VISIT 9	0	0	0	0	0	1	0	0	0	0	2.00
	ND basic	VISIT 10	0	0	0	0	0	1	1	0	0	0	4.00
	ND basic	VISIT 11	0	0	0	0	0	0	0	0	0	0	0.00
01/0106	ND plus	BASELINE (VISIT 2A)	2	1	2	0	3	1	1	1	3	1	30.00
	ND plus	VISIT 3A	2	1	4	0	2	1	1	0	0	1	24.00
	ND plus	VISIT 4	1	0	4	0	1	1	0	0	0	0	14.00
	ND plus	VISIT 5	2	0	1	0	2	1	1	0	0	1	16.00
	ND plus	VISIT 6	1	0	1	0	1	0	1	0	0	0	8.00
	ND plus	VISIT 7	2	0	2	0	1	1	1	0	0	1	16.00
	ND plus	VISIT 8	2	0	1	0	1	1	1	0	0	1	14.00
	ND plus	VISIT 9	2	1	2	0	1	1	1	1	1	1	22.00
	ND plus	VISIT 10	1	0	2	0	1	1	1	1	0	1	16.00
	ND plus	VISIT 11	2	0	2	0	1	1	1	0	0	0	14.00
01/0107	ND plus	BASELINE (VISIT 2A)	2	4	5	3	5	4	4	5	4	5	82.00
	ND plus	VISIT 3A	0	0	-	0	1	1	0	0	0	0	4.44
	ND plus	VISIT 4	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 5	1	0	0	0	0	0	0	0	0	0	2.00
	ND plus	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
01/0107	ND plus	VISIT 9	1	0	1	0	2	1	0	0	0	1	12.00
	ND plus	VISIT 10	0	0	0	0	1	1	0	0	0	0	4.00
	ND plus	VISIT 11	0	0	0	0	1	0	0	0	0	0	2.00
01/0108	ND plus	BASELINE (VISIT 2A)	1	0	2	0	2	4	1	1	3	-	31.11
	ND plus	VISIT 3A	2	0	1	0	2	1	0	0	1	0	14.00
	ND plus	VISIT 4	0	0	1	0	1	0	5	0	0	1	16.00
	ND plus	VISIT 5	1	0	1	0	1	0	0	0	0	0	6.00
	ND plus	VISIT 6	1	0	1	0	2	1	0	0	0	0	10.00
	ND plus	VISIT 7	2	0	1	0	2	1	0	0	0	1	14.00
	ND plus	VISIT 8	0	0	1	0	1	0	0	0	0	0	4.00
	ND plus	VISIT 9	0	0	1	0	1	1	0	0	0	0	6.00
	ND plus	VISIT 10	1	0	1	0	1	1	0	0	0	0	8.00
01/0110	ND basic	BASELINE (VISIT 2A)	2	2	4	2	4	4	3	3	3	2	58.00
	ND basic	VISIT 3A	0	0	3	0	1	0	1	0	0	0	10.00
	ND basic	VISIT 4	0	0	1	0	2	0	1	0	0	0	8.00
	ND basic	VISIT 5	0	0	1	0	1	0	1	0	0	0	6.00
	ND basic	VISIT 6	0	0	0	0	0	0	1	0	0	0	2.00
	ND basic	VISIT 7	1	0	1	0	0	0	1	0	0	1	8.00
	ND basic	VISIT 8	0	0	0	0	0	0	1	0	0	0	2.00
	ND basic	VISIT 9	2	0	1	1	2	2	2	0	0	1	22.00
	ND basic	VISIT 10	0	0	0	0	0	0	1	0	0	0	2.00
01/0111	ND basic	VISIT 11	1	0	0	0	0	0	1	0	0	0	4.00
	ND plus	BASELINE (VISIT 2A)	3	2	3	2	3	3	2	4	3	4	58.00
	ND plus	VISIT 3A	1	0	1	1	1	1	0	0	0	1	12.00
	ND plus	VISIT 4	1	0	1	1	1	1	0	0	1	1	14.00
	ND plus	VISIT 5	1	0	0	0	0	0	0	-	-	-	2.86
	ND plus	VISIT 6	1	0	0	0	0	0	0	0	0	0	2.00
	ND plus	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
01/0112	ND plus	VISIT 10	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 11	0	0	0	0	0	0	0	0	0	0	0.00
01/0112	ND basic	BASELINE (VISIT 2A)	3	1	2	2	4	2	1	1	2	4	44.00
01/0113	ND basic	BASELINE (VISIT 2A)	2	0	2	2	2	2	1	1	2	1	30.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
01/0113	ND basic	VISIT 3A	0	0	4	0	0	0	0	0	0	0	8.00
	ND basic	VISIT 4	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 5	1	0	0	0	0	0	0	0	0	0	2.00
	ND basic	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 7	2	0	1	2	2	3	1	0	0	1	24.00
	ND basic	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 10	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 11	0	0	0	0	0	0	0	0	0	0	0.00
01/0114	ND basic	BASELINE (VISIT 2A)	4	1	4	3	4	4	2	2	2	4	60.00
	ND basic	VISIT 3A	2	0	2	0	2	1	0	0	0	0	14.00
	ND basic	VISIT 4	0	0	0	0	1	0	0	0	0	0	2.00
	ND basic	VISIT 5	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
01/0115	ND plus	BASELINE (VISIT 2A)	3	1	2	2	2	4	2	0	2	2	40.00
	ND plus	VISIT 3A	2	1	2	0	2	2	1	1	2	1	28.00
	ND plus	VISIT 4	1	0	1	0	2	1	0	1	0	1	14.00
	ND plus	VISIT 5	2	0	2	0	1	1	1	0	0	0	14.00
	ND plus	VISIT 6	1	0	1	0	1	1	1	0	0	0	10.00
	ND plus	VISIT 7	1	0	1	0	0	0	1	0	0	0	6.00
	ND plus	VISIT 8	1	0	1	0	0	0	0	0	0	0	4.00
	ND plus	VISIT 9	0	0	1	0	2	2	0	0	0	0	10.00
01/0116	ND plus	VISIT 10	1	0	1	0	0	1	1	0	0	0	8.00
	ND plus	VISIT 11	1	0	1	0	0	1	1	0	0	0	8.00
	ND basic	BASELINE (VISIT 2A)	2	1	3	2	2	4	1	0	4	3	44.00
	ND plus	BASELINE (VISIT 2A)	3	2	1	-	-	-	-	-	-	-	40.00
	ND plus	VISIT 3A	2	1	3	2	3	2	1	1	1	2	36.00
	ND plus	VISIT 4	3	1	2	1	3	2	2	1	0	1	32.00
	ND plus	VISIT 5	2	1	1	-	-	-	-	0	0	1	16.67
	ND plus	VISIT 6	2	1	1	1	2	1	2	1	0	2	26.00
01/0118	ND plus	VISIT 7	4	1	4	2	2	2	3	1	1	2	44.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
01/0118	ND plus	VISIT 8	4	3	4	1	2	2	3	3	3	3	56.00
	ND plus	VISIT 9	4	2	4	2	3	2	3	4	3	1	56.00
	ND plus	VISIT 10	3	3	4	2	3	2	4	1	4	1	54.00
	ND plus	VISIT 11	2	1	4	2	2	2	3	-	-	-	45.71
01/0119	ND basic	BASELINE (VISIT 2A)	2	2	2	2	3	3	2	3	4	5	56.00
	ND basic	VISIT 3A	0	0	2	0	2	1	0	1	2	1	18.00
	ND basic	VISIT 4	1	0	1	0	0	0	0	0	0	0	4.00
	ND basic	VISIT 5	0	0	0	0	1	0	0	0	0	0	2.00
	ND basic	VISIT 6	0	0	0	0	1	0	0	0	0	0	2.00
	ND basic	VISIT 7	0	0	1	0	1	1	0	0	2	0	10.00
	ND basic	VISIT 8	0	0	0	0	0	0	1	0	0	0	2.00
	ND basic	VISIT 9	2	1	2	1	2	1	1	1	2	2	30.00
	ND basic	VISIT 10	2	0	2	2	2	2	1	0	2	2	30.00
	ND basic	VISIT 11	2	0	2	0	2	1	1	0	2	1	22.00
01/0121	ND plus	BASELINE (VISIT 2A)	2	1	2	2	1	3	4	1	2	1	38.00
	ND plus	VISIT 3A	0	0	0	1	0	0	0	0	0	0	2.00
	ND plus	VISIT 4	1	0	1	1	0	2	0	0	0	0	10.00
	ND plus	VISIT 5	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
01/0122	ND plus	BASELINE (VISIT 2A)	2	0	1	0	0	1	1	0	2	0	14.00
	ND plus	VISIT 3A	0	0	1	0	2	1	0	0	0	0	8.00
	ND plus	VISIT 4	0	0	0	0	1	0	0	0	0	0	2.00
	ND plus	VISIT 5	1	0	0	0	0	0	0	0	0	0	2.00
	ND plus	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 7	1	0	0	0	0	0	0	0	0	0	2.00
	ND plus	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 10	1	0	0	0	0	0	0	0	0	0	2.00
	ND plus	VISIT 11	0	0	0	0	0	0	0	0	0	0	0.00
01/0123	ND plus	BASELINE (VISIT 2A)	2	2	2	1	3	4	2	2	3	2	46.00
	ND plus	VISIT 3A	2	2	1	2	3	4	1	3	2	2	44.00
	ND plus	VISIT 4	2	1	3	2	3	3	1	2	3	3	46.00
	ND plus	VISIT 5	2	1	2	1	3	4	1	1	3	1	38.00
	ND plus	VISIT 6	2	1	2	1	2	2	2	1	2	2	34.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
01/0123	ND plus	VISIT 7	2	2	3	1	3	4	1	1	2	3	44.00
	ND plus	VISIT 8	3	1	2	-	-	-	-	-	-	-	40.00
	ND plus	VISIT 9	2	1	2	1	2	4	2	-	-	-	40.00
	ND plus	VISIT 10	4	3	4	4	4	4	3	4	4	3	74.00
01/0124	ND plus	BASELINE (VISIT 2A)	2	0	3	0	2	2	1	3	3	1	34.00
01/0125	SC	BASELINE (VISIT 2A)	2	2	3	0	3	0	3	5	2	1	42.00
	SC	VISIT 4	1	0	1	0	2	1	0	3	1	1	20.00
	SC	VISIT 5	0	0	1	0	0	0	0	0	0	0	2.00
	SC	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 7	0	0	1	0	0	0	0	0	0	0	2.00
	SC	VISIT 8	1	0	1	0	0	0	0	0	0	0	4.00
	SC	VISIT 9	2	0	1	0	0	0	0	0	0	1	8.00
	SC	VISIT 10	4	1	2	0	2	0	2	-	2	2	33.33
	SC	VISIT 11	2	0	1	0	0	0	0	0	0	1	8.00
01/0126	ND basic	BASELINE (VISIT 2A)	5	2	5	0	5	5	3	5	5	5	80.00
	ND basic	VISIT 3A	1	0	2	1	2	2	1	-	0	1	22.22
	ND basic	VISIT 4	2	1	1	0	2	1	1	-	-	0	20.00
	ND basic	VISIT 5	1	0	4	0	2	1	1	-	0	0	20.00
	ND basic	VISIT 6	1	0	0	0	2	2	1	-	0	0	13.33
	ND basic	VISIT 7	1	0	0	0	1	0	0	0	0	0	4.00
	ND basic	VISIT 8	0	0	0	0	1	0	0	0	0	0	2.00
	ND basic	VISIT 9	1	0	1	0	1	1	1	0	0	0	10.00
	ND basic	VISIT 10	1	0	3	0	1	1	0	0	0	2	16.00
	ND basic	VISIT 11	1	0	1	0	2	1	1	0	0	0	12.00
01/0127	ND plus	BASELINE (VISIT 2A)	3	2	2	2	4	4	1	0	3	2	46.00
	ND plus	VISIT 3A	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 4	1	0	0	0	0	1	0	0	0	0	4.00
	ND plus	VISIT 5	1	0	1	0	0	1	1	0	1	1	12.00
	ND plus	VISIT 6	2	0	1	0	1	1	0	0	1	1	14.00
	ND plus	VISIT 7	1	0	1	0	0	0	0	0	0	0	4.00
	ND plus	VISIT 8	2	0	1	0	1	1	1	0	0	1	14.00
	ND plus	VISIT 9	3	1	1	0	1	1	1	0	0	1	18.00
	ND plus	VISIT 10	2	0	1	0	2	1	1	1	2	1	22.00
	ND plus	VISIT 11	1	1	2	0	0	0	0	0	0	0	8.00
01/0128	ND plus	BASELINE (VISIT 2A)	2	1	2	3	3	3	2	2	3	4	50.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
01/0128	ND plus	VISIT 3A	1	0	3	0	1	1	0	0	0	1	14.00
	ND plus	VISIT 4	1	0	1	0	1	1	0	0	0	0	8.00
	ND plus	VISIT 5	0	0	2	0	1	1	0	0	0	0	8.00
	ND plus	VISIT 6	1	0	2	0	0	1	0	0	0	0	8.00
	ND plus	VISIT 7	2	0	2	0	0	0	0	0	0	0	8.00
	ND plus	VISIT 8	1	0	1	0	0	0	0	0	0	0	4.00
	ND plus	VISIT 9	1	0	1	0	1	0	0	0	2	0	10.00
	ND plus	VISIT 10	1	0	1	0	0	0	0	0	2	0	8.00
	ND plus	VISIT 11	2	1	1	0	1	1	1	0	2	1	20.00
01/0129	SC	BASELINE (VISIT 2A)	2	1	-	2	2	2	1	4	2	5	46.67
	SC	VISIT 4	2	0	4	0	0	0	1	0	0	0	14.00
	SC	VISIT 5	0	0	4	0	0	0	0	0	0	0	8.00
	SC	VISIT 6	0	0	0	0	0	0	1	0	0	0	2.00
	SC	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 9	2	0	0	0	0	0	1	0	0	0	6.00
	SC	VISIT 10	2	2	3	1	2	2	1	0	2	2	34.00
	SC	VISIT 11	0	0	0	0	0	-	0	0	0	0	0.00
01/0130	ND basic	BASELINE (VISIT 2A)	3	1	3	2	2	2	1	3	2	0	38.00
	ND basic	VISIT 3A	0	0	1	0	0	1	1	0	0	0	6.00
	ND basic	VISIT 4	0	0	1	0	0	0	1	0	0	0	4.00
	ND basic	VISIT 5	0	0	3	0	1	0	1	0	0	0	10.00
	ND basic	VISIT 6	0	0	1	0	0	0	1	0	0	0	4.00
	ND basic	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 8	0	0	-	0	1	0	1	0	0	0	4.44
	ND basic	VISIT 9	1	0	0	0	1	0	1	0	0	-	6.67
	ND basic	VISIT 10	0	0	0	0	1	0	1	0	0	0	4.00
	ND basic	VISIT 11	0	0	4	0	1	0	1	0	0	0	12.00
01/0131	ND plus	BASELINE (VISIT 2A)	4	2	4	4	5	5	2	3	3	5	74.00
	ND plus	VISIT 3A	0	0	0	0	0	1	1	0	0	0	4.00
	ND plus	VISIT 4	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 5	0	0	0	0	0	1	0	0	0	0	2.00
	ND plus	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 8	1	0	0	0	0	0	0	0	0	0	2.00
	ND plus	VISIT 9	1	0	1	0	0	0	0	0	0	0	4.00
	ND plus	VISIT 10	0	0	0	0	0	0	0	0	0	0	0.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
01/0131	ND plus	VISIT 11	0	0	0	0	0	0	0	0	0	0	0.00
01/0132	SC	BASELINE (VISIT 2A)	2	1	3	2	2	3	2	1	2	2	40.00
	SC	VISIT 4	1	0	1	0	2	3	0	-	0	0	15.56
	SC	VISIT 5	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 6	1	0	0	0	0	0	0	0	0	0	2.00
	SC	VISIT 7	1	0	0	0	1	1	0	0	0	0	6.00
	SC	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 9	1	0	0	0	0	0	0	0	0	0	2.00
	SC	VISIT 10	1	0	1	0	0	0	0	0	0	0	4.00
	SC	VISIT 11	1	0	0	0	0	1	0	1	0	0	6.00
01/0133	ND plus	BASELINE (VISIT 2A)	3	1	1	1	3	3	1	0	3	2	36.00
01/0134	ND basic	BASELINE (VISIT 2A)	2	1	4	1	3	1	1	3	2	1	38.00
01/0135	ND plus	BASELINE (VISIT 2A)	2	1	2	1	2	2	1	1	3	1	32.00
	ND plus	VISIT 3A	1	0	4	0	1	1	1	0	2	1	22.00
	ND plus	VISIT 4	1	0	0	0	0	1	0	0	0	0	4.00
	ND plus	VISIT 5	1	0	1	0	1	1	1	0	0	0	10.00
	ND plus	VISIT 6	2	0	2	1	2	2	1	0	2	2	28.00
	ND plus	VISIT 7	1	0	1	0	1	1	0	0	2	1	14.00
	ND plus	VISIT 8	1	0	1	0	1	2	1	0	0	1	14.00
	ND plus	VISIT 9	2	0	3	0	2	2	2	0	2	1	28.00
	ND plus	VISIT 10	3	1	3	0	2	3	2	1	1	1	34.00
	ND plus	VISIT 11	2	1	2	0	1	2	1	1	1	1	24.00
01/0136	ND basic	BASELINE (VISIT 2A)	3	2	3	2	3	3	2	4	4	3	58.00
	ND basic	VISIT 3A	2	0	1	1	3	3	1	1	3	3	36.00
	ND basic	VISIT 4	2	0	1	1	2	1	1	0	1	1	20.00
	ND basic	VISIT 5	3	2	3	1	3	3	1	0	2	3	42.00
	ND basic	VISIT 6	3	1	1	1	2	3	1	1	0	2	30.00
	ND basic	VISIT 7	3	0	3	2	3	3	1	0	3	3	42.00
	ND basic	VISIT 8	3	1	2	2	3	4	1	0	0	3	38.00
	ND basic	VISIT 9	4	2	3	2	4	4	1	1	3	1	50.00
	ND basic	VISIT 10	3	1	3	2	3	4	1	0	3	1	42.00
	ND basic	VISIT 11	4	0	3	2	3	4	1	0	2	3	44.00
01/0137	ND plus	BASELINE (VISIT 2A)	1	0	0	1	0	0	0	0	0	0	4.00
	ND plus	VISIT 3A	0	0	2	0	0	0	0	0	0	0	4.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
01/0137	ND plus	VISIT 4	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 5	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 8	1	0	0	0	0	0	0	0	0	0	2.00
	ND plus	VISIT 9	1	0	0	0	0	0	0	0	0	0	2.00
	ND plus	VISIT 10	1	0	0	0	0	0	0	0	0	0	2.00
	ND plus	VISIT 11	0	0	0	0	0	0	0	0	0	0	0.00
01/0138	SC	BASELINE (VISIT 2A)	0	0	0	0	0	0	0	1	0	0	2.00
	SC	VISIT 4	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 5	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 10	0	0	0	0	0	0	0	0	0	0	0.00
01/0139	ND plus	BASELINE (VISIT 2A)	4	1	3	2	2	2	1	3	1	2	42.00
	ND plus	VISIT 3A	0	0	1	0	1	0	0	0	0	0	4.00
	ND plus	VISIT 4	0	0	0	0	1	0	0	0	0	0	2.00
	ND plus	VISIT 5	1	0	1	0	1	0	0	0	0	0	6.00
	ND plus	VISIT 6	1	0	1	0	1	0	0	0	0	0	6.00
	ND plus	VISIT 7	1	0	1	0	1	1	1	0	0	0	10.00
	ND plus	VISIT 8	2	0	1	0	2	2	0	0	1	1	18.00
	ND plus	VISIT 9	1	0	1	0	1	1	0	0	0	0	8.00
01/0140	ND plus	VISIT 10	0	0	1	0	1	1	0	0	0	0	6.00
	ND basic	BASELINE (VISIT 2A)	2	1	2	0	3	1	2	1	2	1	30.00
	ND basic	VISIT 3A	2	0	1	0	2	1	1	0	2	1	20.00
	ND basic	VISIT 4	2	0	1	0	2	2	1	1	2	2	26.00
	ND basic	VISIT 5	1	0	1	0	1	0	0	0	0	0	6.00
	ND basic	VISIT 6	1	0	1	0	1	1	1	0	0	0	10.00
	ND basic	VISIT 7	1	0	1	0	1	1	1	0	0	0	10.00
	ND basic	VISIT 8	1	0	1	0	1	1	1	0	0	0	10.00
	ND basic	VISIT 9	2	0	1	0	1	1	1	0	0	0	12.00
	ND basic	VISIT 10	2	0	1	0	2	1	1	1	2	1	22.00
	ND basic	VISIT 11	1	0	1	0	2	1	1	0	0	0	12.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
01/0141	SC	BASELINE (VISIT 2A)	5	2	4	3	4	4	3	4	4	5	76.00
	SC	VISIT 4	1	0	1	0	2	2	0	0	2	1	18.00
	SC	VISIT 5	1	0	1	0	2	1	0	0	0	0	10.00
	SC	VISIT 6	0	0	1	0	0	0	0	0	0	0	2.00
	SC	VISIT 7	1	0	1	0	0	1	0	0	0	0	6.00
	SC	VISIT 8	0	0	0	0	0	0	1	0	0	0	2.00
	SC	VISIT 9	1	0	1	0	0	0	0	0	0	0	4.00
	SC	VISIT 10	1	0	0	0	0	0	0	0	0	0	2.00
	SC	VISIT 11	1	0	1	0	0	0	0	0	0	0	4.00
01/0142	ND plus	BASELINE (VISIT 2A)	2	3	3	1	2	3	1	2	2	2	42.00
	ND plus	VISIT 3A	1	0	1	0	1	1	0	0	0	0	8.00
	ND plus	VISIT 4	1	0	1	0	2	2	0	0	0	0	12.00
	ND plus	VISIT 6	1	0	1	0	1	1	0	0	0	0	8.00
	ND plus	VISIT 7	2	0	1	0	2	3	0	0	0	0	16.00
	ND plus	VISIT 8	1	0	1	0	1	1	1	0	0	1	12.00
	ND plus	VISIT 9	2	0	1	0	1	3	0	0	0	1	16.00
	ND plus	VISIT 10	2	0	2	0	3	4	1	0	0	1	26.00
	ND plus	VISIT 11	2	0	1	0	1	1	1	-	1	1	17.78
01/0143	ND plus	BASELINE (VISIT 2A)	3	1	3	1	2	2	1	4	3	3	46.00
	ND plus	VISIT 3A	0	0	1	0	2	1	1	1	0	1	14.00
	ND plus	VISIT 4	2	0	1	0	2	2	1	1	0	1	20.00
	ND plus	VISIT 5	1	0	1	0	2	1	1	1	0	1	16.00
	ND plus	VISIT 6	1	0	1	0	2	1	1	1	0	1	16.00
	ND plus	VISIT 7	1	0	1	0	1	1	1	1	0	0	12.00
	ND plus	VISIT 8	1	0	1	0	1	1	1	0	0	0	10.00
	ND plus	VISIT 9	1	0	1	0	1	1	1	1	0	0	12.00
	ND plus	VISIT 10	1	0	1	0	1	1	1	1	0	0	12.00
	ND plus	VISIT 11	0	0	1	0	0	0	1	0	0	0	4.00
01/0144	ND basic	BASELINE (VISIT 2A)	2	1	3	2	4	2	2	2	2	2	44.00
	ND basic	VISIT 3A	0	0	1	0	0	0	0	0	0	0	2.00
	ND basic	VISIT 4	0	0	-	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 5	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 10	2	1	3	0	2	1	1	0	0	1	22.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
01/0144	ND basic	VISIT 11	0	0	0	0	0	0	-	0	0	0	0.00
01/0145	ND plus	BASELINE (VISIT 2A)	2	1	1	1	3	4	2	1	1	4	40.00
	ND plus	VISIT 3A	2	1	2	0	1	1	0	-	2	1	22.22
	ND plus	VISIT 4	1	0	1	0	1	0	0	-	0	0	6.67
	ND plus	VISIT 5	1	0	1	0	1	0	0	-	0	0	6.67
	ND plus	VISIT 6	1	0	0	0	1	0	0	-	0	0	4.44
	ND plus	VISIT 7	2	0	0	0	0	0	0	0	0	0	4.00
	ND plus	VISIT 8	1	0	2	0	1	0	0	-	0	0	8.89
	ND plus	VISIT 9	1	0	1	0	1	0	0	-	0	0	6.67
	ND plus	VISIT 10	2	0	2	1	2	2	1	0	0	0	20.00
	ND plus	VISIT 11	1	0	0	0	1	0	0	-	0	0	4.44
01/0146	SC	BASELINE (VISIT 2A)	3	1	1	0	3	2	1	1	3	3	36.00
	SC	VISIT 4	0	0	1	0	1	0	1	0	0	0	6.00
	SC	VISIT 5	2	0	0	0	0	1	0	0	0	1	8.00
	SC	VISIT 6	2	0	1	0	0	1	1	0	0	1	12.00
	SC	VISIT 7	3	1	1	1	3	3	1	1	0	1	30.00
	SC	VISIT 8	2	0	1	0	0	1	1	0	0	1	12.00
	SC	VISIT 9	2	0	1	0	2	1	1	0	0	0	14.00
	SC	VISIT 10	2	0	1	0	2	1	1	0	0	1	16.00
	SC	VISIT 11	2	0	1	0	2	1	1	0	0	1	16.00
01/0147	ND plus	BASELINE (VISIT 2A)	2	0	4	2	2	4	1	-	0	1	35.56
	ND plus	VISIT 3A	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 4	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 5	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 10	1	0	0	0	0	0	0	0	0	0	2.00
	ND plus	VISIT 11	0	0	0	0	0	0	0	0	0	0	0.00
01/0148	ND plus	BASELINE (VISIT 2A)	4	1	3	3	1	4	1	2	3	2	48.00
	ND plus	VISIT 3A	2	0	2	0	1	1	1	0	0	1	16.00
	ND plus	VISIT 4	2	0	1	0	1	1	1	1	0	1	16.00
	ND plus	VISIT 5	1	0	1	0	0	1	1	0	0	0	8.00
	ND plus	VISIT 6	1	0	0	0	1	1	0	0	0	0	6.00
	ND plus	VISIT 7	2	0	0	0	1	0	1	0	0	0	8.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
01/0148	ND plus	VISIT 8	2	0	0	0	0	1	0	0	0	0	6.00
	ND plus	VISIT 9	2	0	1	0	1	1	2	0	0	1	16.00
	ND plus	VISIT 10	2	0	1	0	0	1	0	0	0	0	8.00
	ND plus	VISIT 11	2	0	1	0	0	1	2	0	0	0	12.00
01/0149	ND plus	BASELINE (VISIT 2A)	3	2	4	0	2	5	3	4	4	4	62.00
	ND plus	VISIT 3A	0	0	1	0	0	0	0	0	0	0	2.00
	ND plus	VISIT 4	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 5	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 8	0	0	4	0	0	0	0	0	0	0	8.00
	ND plus	VISIT 9	1	0	1	0	0	0	0	0	0	0	4.00
	ND plus	VISIT 10	0	0	1	0	0	0	0	0	0	0	2.00
	ND plus	VISIT 11	1	0	2	0	1	1	1	0	0	0	12.00
01/0150		BASELINE (VISIT 2A)	2	0	3	1	2	2	2	1	2	1	32.00
01/0151	ND basic	BASELINE (VISIT 2A)	4	1	3	3	3	3	3	4	4	4	64.00
	ND basic	VISIT 3A	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 4	0	0	0	-	-	-	-	0	0	0	0.00
	ND basic	VISIT 5	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 9	1	0	0	0	0	0	1	0	0	0	4.00
	ND basic	VISIT 10	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 11	0	0	0	-	-	-	-	0	0	0	0.00
01/0152	SC	BASELINE (VISIT 2A)	2	1	1	0	1	1	1	-	2	1	22.22
	SC	VISIT 4	1	0	4	0	2	1	1	0	0	1	20.00
	SC	VISIT 5	2	0	4	0	1	1	1	-	2	0	24.44
	SC	VISIT 6	1	0	4	0	1	1	1	-	2	0	22.22
	SC	VISIT 7	0	0	1	0	1	1	1	-	0	0	8.89
	SC	VISIT 8	2	0	2	0	1	1	1	1	2	1	22.00
	SC	VISIT 9	2	0	2	1	1	1	1	-	2	1	24.44
	SC	VISIT 10	2	1	2	1	2	2	1	1	0	2	28.00
	SC	VISIT 11	2	0	2	0	0	1	1	-	2	-	20.00
01/0153	ND basic	BASELINE (VISIT 2A)	3	1	3	0	2	3	1	0	4	0	34.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
01/0153	ND basic	VISIT 3A	0	0	2	0	0	1	0	0	0	1	8.00
	ND basic	VISIT 4	2	1	3	1	2	-	-	0	2	0	27.50
	ND basic	VISIT 5	0	0	0	0	1	0	0	0	0	0	2.00
	ND basic	VISIT 6	1	0	1	3	0	3	0	0	0	1	18.00
	ND basic	VISIT 7	1	0	0	0	0	2	1	0	0	0	8.00
	ND basic	VISIT 8	0	0	1	0	1	1	0	0	0	0	6.00
	ND basic	VISIT 9	0	0	1	0	1	2	0	0	0	0	8.00
	ND basic	VISIT 10	2	0	1	0	1	1	1	0	0	0	12.00
	ND basic	VISIT 11	2	0	1	0	0	0	1	0	0	0	8.00
02/0201	ND plus	BASELINE (VISIT 2A)	2	0	1	0	2	0	2	1	2	3	26.00
	ND plus	VISIT 3A	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 4	1	0	0	0	1	0	0	0	0	0	4.00
	ND plus	VISIT 5	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 10	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 11	0	0	0	0	0	0	0	0	0	0	0.00
02/0202	ND basic	BASELINE (VISIT 2A)	5	4	4	5	5	5	5	5	4	5	94.00
	ND basic	VISIT 3A	1	0	0	0	0	0	0	0	0	0	2.00
02/0203	ND basic	BASELINE (VISIT 2A)	3	1	3	3	4	4	3	3	4	5	66.00
	ND basic	VISIT 3A	0	0	3	0	2	3	0	0	2	1	22.00
	ND basic	VISIT 4	2	1	4	1	3	3	1	1	0	3	38.00
	ND basic	VISIT 5	2	0	3	1	2	3	0	1	0	1	26.00
	ND basic	VISIT 6	1	0	1	0	2	1	0	0	0	1	12.00
	ND basic	VISIT 7	1	1	3	0	3	3	1	0	0	3	30.00
	ND basic	VISIT 8	2	0	2	0	2	2	1	1	0	1	22.00
	ND basic	VISIT 9	2	1	3	0	2	3	2	1	2	1	34.00
	ND basic	VISIT 10	3	1	3	1	2	3	2	1	2	1	38.00
	ND basic	VISIT 11	1	0	1	0	2	1	1	0	0	0	12.00
02/0204	ND basic	BASELINE (VISIT 2A)	0	0	2	0	2	0	0	-	2	3	20.00
02/0205	ND basic	BASELINE (VISIT 2A)	4	3	4	1	4	4	2	3	3	5	66.00
	ND basic	VISIT 3A	0	0	4	0	1	0	1	0	0	0	12.00
	ND basic	VISIT 4	0	0	2	0	1	0	0	0	0	0	6.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
02/0205	ND basic	VISIT 5	0	0	2	0	0	0	0	0	0	0	4.00
	ND basic	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 10	1	0	0	0	0	0	0	0	0	0	2.00
	ND basic	VISIT 11	1	0	0	0	0	0	0	0	0	0	2.00
02/0206	ND plus	BASELINE (VISIT 2A)	2	2	3	3	3	4	2	2	3	2	52.00
	ND plus	VISIT 3A	0	0	1	0	2	2	1	0	0	0	12.00
	ND plus	VISIT 4	2	1	2	1	2	2	1	1	0	5	34.00
	ND plus	VISIT 5	1	0	1	1	2	1	1	-	0	0	15.56
	ND plus	VISIT 6	1	0	0	1	1	1	0	-	0	0	8.89
	ND plus	VISIT 7	1	0	1	0	0	1	1	-	0	0	8.89
	ND plus	VISIT 9	0	0	1	0	1	1	1	0	0	0	8.00
	ND plus	VISIT 10	2	0	1	1	2	1	1	-	0	0	17.78
	ND plus	VISIT 11	1	0	1	0	1	1	1	-	0	0	11.11
02/0207		BASELINE (VISIT 2A)	4	1	3	1	2	3	1	4	4	2	50.00
02/0208	ND plus	BASELINE (VISIT 2A)	2	0	1	1	2	2	1	0	2	1	24.00
	ND plus	VISIT 3A	1	0	1	0	2	1	0	0	2	1	16.00
	ND plus	VISIT 4	2	0	1	1	2	1	0	0	0	1	16.00
	ND plus	VISIT 5	3	1	3	0	3	4	1	-	3	5	51.11
	ND plus	VISIT 6	1	0	0	0	1	0	0	-	0	0	4.44
	ND plus	VISIT 7	0	0	1	0	1	0	1	0	2	0	10.00
	ND plus	VISIT 8	0	0	4	0	1	0	0	0	0	0	10.00
	ND plus	VISIT 9	0	0	1	0	1	1	1	-	2	1	15.56
	ND plus	VISIT 10	2	0	3	0	2	1	1	1	2	1	26.00
	ND plus	VISIT 11	1	0	1	1	2	2	1	-	1	1	22.22
02/0209	ND plus	BASELINE (VISIT 2A)	2	1	1	0	0	1	1	0	0	0	12.00
	ND plus	VISIT 3A	1	1	1	0	1	0	1	1	1	0	14.00
	ND plus	VISIT 4	2	0	1	0	1	0	1	0	0	0	10.00
	ND plus	VISIT 5	1	0	1	0	1	0	1	1	0	0	10.00
	ND plus	VISIT 6	0	0	1	0	1	0	1	0	0	0	6.00
	ND plus	VISIT 7	0	0	1	0	1	0	0	0	0	0	4.00
	ND plus	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 10	0	0	0	0	0	0	0	0	0	0	0.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
02/0209	ND plus	VISIT 11	0	0	0	0	0	0	0	0	0	0	0.00
02/0210		BASELINE (VISIT 2A)	4	2	3	2	2	2	1	-	3	3	48.89
02/0211	ND basic	BASELINE (VISIT 2A)	2	1	2	0	0	1	1	1	2	1	22.00
	ND basic	VISIT 3A	2	0	2	1	2	1	2	1	2	1	28.00
02/0212	SC	BASELINE (VISIT 2A)	2	1	1	1	2	2	2	3	3	2	38.00
	SC	VISIT 4	2	2	1	0	2	1	1	0	0	1	20.00
	SC	VISIT 5	2	1	1	0	2	1	1	0	1	1	20.00
	SC	VISIT 6	1	0	1	0	1	0	1	0	0	0	8.00
	SC	VISIT 7	2	2	1	0	2	0	0	0	0	0	14.00
	SC	VISIT 8	2	2	0	0	2	0	1	0	0	0	14.00
	SC	VISIT 9	2	0	1	0	1	1	0	0	0	0	10.00
	SC	VISIT 10	3	1	1	0	3	3	1	1	1	1	30.00
	SC	VISIT 11	2	2	1	0	0	0	1	0	0	0	12.00
02/0213	ND plus	BASELINE (VISIT 2A)	2	2	3	0	1	1	1	2	3	2	34.00
02/0214	ND plus	BASELINE (VISIT 2A)	3	2	3	1	3	2	1	4	3	2	48.00
	ND plus	VISIT 3A	2	0	4	1	2	2	0	0	0	0	22.00
	ND plus	VISIT 4	2	0	0	1	1	1	0	0	0	0	10.00
	ND plus	VISIT 6	2	0	1	1	2	2	1	0	0	0	18.00
	ND plus	VISIT 7	0	0	1	1	2	2	0	0	0	0	12.00
	ND plus	VISIT 9	0	0	1	0	1	0	0	0	0	0	4.00
	ND plus	VISIT 11	2	0	1	1	2	2	0	3	0	0	22.00
02/0215		BASELINE (VISIT 2A)	3	1	1	1	1	1	1	1	1	2	26.00
02/0216	ND plus	BASELINE (VISIT 2A)	2	2	4	1	5	2	1	5	3	3	56.00
	ND plus	VISIT 3A	1	0	2	1	2	1	1	1	1	1	22.00
	ND plus	VISIT 5	2	0	2	1	0	1	1	1	0	1	18.00
02/0217	SC	BASELINE (VISIT 2A)	4	4	4	5	5	5	3	4	3	4	82.00
	SC	VISIT 4	0	0	0	0	0	0	0	-	0	0	0.00
	SC	VISIT 5	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 9	0	0	0	0	1	0	0	0	0	0	2.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
02/0217	SC	VISIT 10	1	0	0	0	0	0	0	0	0	0	2.00
	SC	VISIT 11	0	0	0	0	0	0	0	0	0	0	0.00
02/0218	ND basic	BASELINE (VISIT 2A)	3	1	2	1	2	2	1	2	2	2	36.00
02/0219	ND basic	BASELINE (VISIT 2A)	2	2	3	1	2	2	1	0	3	1	34.00
	ND basic	VISIT 3A	2	0	2	0	2	1	1	0	2	1	22.00
	ND basic	VISIT 4	1	0	3	0	2	2	1	0	0	0	18.00
	ND basic	VISIT 5	1	0	3	0	2	1	1	1	2	1	24.00
	ND basic	VISIT 6	1	0	2	0	2	1	1	0	0	0	14.00
	ND basic	VISIT 7	1	0	2	0	2	1	0	0	0	0	12.00
	ND basic	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 9	2	0	1	0	2	1	1	0	0	1	16.00
	ND basic	VISIT 10	2	0	2	0	1	1	1	0	0	0	14.00
	ND basic	VISIT 11	0	0	2	0	2	1	0	0	0	0	10.00
02/0220	SC	BASELINE (VISIT 2A)	3	1	2	3	3	1	3	4	3	5	56.00
	SC	VISIT 4	2	0	4	0	2	3	1	0	2	1	30.00
	SC	VISIT 5	2	0	3	0	2	1	1	0	2	1	24.00
	SC	VISIT 6	2	0	3	0	2	0	0	0	2	0	18.00
	SC	VISIT 7	2	0	1	0	2	1	0	0	2	1	18.00
	SC	VISIT 8	1	0	2	0	3	1	0	0	0	1	16.00
	SC	VISIT 9	2	0	4	0	0	1	0	0	1	0	16.00
	SC	VISIT 10	3	0	2	0	2	1	1	0	2	-	24.44
	SC	VISIT 11	2	0	1	0	2	1	0	0	1	1	16.00
02/0221	ND plus	BASELINE (VISIT 2A)	4	2	3	1	4	1	2	5	2	5	58.00
02/0222	ND plus	BASELINE (VISIT 2A)	4	2	4	5	4	4	3	5	4	5	80.00
02/0223	ND basic	BASELINE (VISIT 2A)	3	1	1	1	3	3	4	2	4	2	48.00
	ND basic	VISIT 3A	0	0	4	0	2	2	0	0	2	1	22.00
	ND basic	VISIT 4	2	0	1	0	2	2	0	0	1	1	18.00
	ND basic	VISIT 5	0	0	1	0	2	1	1	0	0	0	10.00
	ND basic	VISIT 6	1	0	1	0	2	2	1	0	0	1	16.00
	ND basic	VISIT 7	1	0	1	0	2	1	1	0	0	0	12.00
	ND basic	VISIT 8	0	0	0	0	1	0	0	0	0	0	2.00
	ND basic	VISIT 9	0	0	1	0	0	1	0	0	0	0	4.00
	ND basic	VISIT 10	0	0	0	0	0	0	1	0	0	0	2.00
	ND basic	VISIT 11	1	0	0	0	0	0	1	0	0	0	4.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
02/0224	ND plus	BASELINE (VISIT 2A)	3	2	4	5	5	4	4	5	1	4	74.00
04/0401	SC	BASELINE (VISIT 2A)	3	1	4	1	4	3	1	3	5	5	60.00
	SC	VISIT 4	2	0	3	0	1	0	0	0	3	0	18.00
	SC	VISIT 5	0	0	2	0	0	0	0	0	0	0	4.00
	SC	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 10	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 11	0	0	0	0	0	0	0	0	0	0	0.00
06/0602	ND plus	BASELINE (VISIT 2A)	2	0	0	0	4	4	3	1	4	4	44.00
	ND plus	VISIT 3A	1	0	1	0	3	1	0	0	2	1	18.00
	ND plus	VISIT 4	2	0	1	0	3	0	0	0	0	0	12.00
	ND plus	VISIT 5	1	0	1	1	0	0	0	0	0	0	6.00
	ND plus	VISIT 6	0	0	0	0	2	0	0	0	0	0	4.00
	ND plus	VISIT 7	0	0	-	1	1	2	0	0	0	0	8.89
	ND plus	VISIT 8	0	0	0	0	1	0	0	1	0	0	4.00
06/0604	ND basic	BASELINE (VISIT 2A)	3	1	3	3	3	1	1	3	3	4	50.00
06/0605	ND plus	BASELINE (VISIT 2A)	2	1	1	1	3	3	1	3	4	3	44.00
06/0606	SC	BASELINE (VISIT 2A)	2	0	1	0	2	1	3	3	3	1	32.00
	SC	VISIT 4	2	1	2	0	2	2	2	2	4	2	38.00
	SC	VISIT 5	4	2	3	1	2	2	4	0	3	2	46.00
	SC	VISIT 6	2	1	2	1	2	1	3	2	4	1	38.00
	SC	VISIT 7	2	1	3	0	2	2	5	3	4	2	48.00
	SC	VISIT 8	2	1	3	0	2	1	1	-	3	1	31.11
	SC	VISIT 9	3	2	2	0	2	2	2	0	3	2	36.00
	SC	VISIT 10	3	1	1	0	2	1	2	2	3	1	32.00
	SC	VISIT 11	1	1	3	0	2	2	1	1	2	1	28.00
06/0607	ND plus	BASELINE (VISIT 2A)	3	2	2	1	2	2	3	-	0	2	37.78
	ND plus	VISIT 3A	1	0	3	1	2	2	2	-	0	1	26.67
	ND plus	VISIT 4	2	0	0	1	2	0	1	-	0	0	13.33
	ND plus	VISIT 5	2	2	0	1	2	2	1	-	-	-	28.57
	ND plus	VISIT 6	2	2	1	1	2	2	-	-	-	-	33.33
	ND plus	VISIT 7	1	0	3	1	2	1	1	-	0	0	20.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
06/0607	ND plus	VISIT 8	1	0	1	0	2	1	1	-	0	1	15.56
	ND plus	VISIT 9	3	1	1	0	2	0	1	-	0	2	22.22
	ND plus	VISIT 10	1	0	1	0	0	0	1	-	0	0	6.67
	ND plus	VISIT 11	1	0	0	0	2	2	1	-	0	0	13.33
06/0608	SC	BASELINE (VISIT 2A)	2	0	4	0	-	0	1	-	2	4	32.50
06/0609	ND basic	BASELINE (VISIT 2A)	2	1	2	1	3	1	2	-	3	2	37.78
06/0610	ND plus	BASELINE (VISIT 2A)	3	2	3	1	4	4	2	3	3	2	54.00
	ND plus	VISIT 3A	1	2	3	1	3	2	1	3	3	2	42.00
	ND plus	VISIT 4	0	0	1	0	1	1	0	0	0	0	6.00
	ND plus	VISIT 5	2	0	3	1	2	1	1	2	3	1	32.00
	ND plus	VISIT 6	0	0	3	0	2	1	0	0	3	0	18.00
	ND plus	VISIT 7	0	0	3	0	3	3	0	0	2	1	24.00
	ND plus	VISIT 8	0	0	1	0	1	1	0	0	0	0	6.00
	ND plus	VISIT 11	0	0	2	0	1	2	1	1	2	1	20.00
06/0611		BASELINE (VISIT 2A)	4	2	3	3	5	4	2	5	5	5	76.00
06/0612	ND plus	BASELINE (VISIT 2A)	1	1	2	1	2	2	3	1	1	1	30.00
	ND plus	VISIT 3A	1	1	4	1	1	2	0	1	1	1	26.00
	ND plus	VISIT 4	2	0	1	0	2	1	0	0	2	1	18.00
	ND plus	VISIT 5	1	0	1	0	0	1	0	0	2	1	12.00
	ND plus	VISIT 6	1	0	0	0	0	1	0	0	0	0	4.00
	ND plus	VISIT 7	0	0	1	0	1	1	0	0	0	0	6.00
	ND plus	VISIT 8	1	0	0	0	1	1	0	0	0	0	6.00
	ND plus	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 10	0	0	0	0	1	1	0	0	0	0	4.00
	ND plus	VISIT 11	1	0	1	0	0	1	0	0	0	0	6.00
06/0613	SC	BASELINE (VISIT 2A)	3	2	4	2	2	2	2	5	4	3	58.00
	SC	VISIT 4	1	0	1	0	1	0	1	1	0	0	10.00
	SC	VISIT 5	1	0	2	0	1	0	1	0	0	0	10.00
	SC	VISIT 6	1	0	-	0	1	0	1	1	0	0	8.89
	SC	VISIT 8	1	0	1	0	0	0	1	1	0	0	8.00
	SC	VISIT 9	1	0	1	0	1	0	1	1	0	0	10.00
	SC	VISIT 10	1	0	1	0	1	0	1	1	0	0	10.00
	SC	VISIT 11	0	1	1	0	1	0	1	1	0	0	10.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
06/0614	ND plus	BASELINE (VISIT 2A)	4	1	3	1	4	3	3	5	3	4	62.00
	ND plus	VISIT 3A	2	0	2	1	2	1	1	3	2	2	32.00
	ND plus	VISIT 4	1	0	2	1	1	1	0	0	2	1	18.00
	ND plus	VISIT 5	3	1	3	1	3	3	2	5	3	3	54.00
	ND plus	VISIT 6	2	0	3	1	2	1	1	2	2	2	32.00
	ND plus	VISIT 7	2	1	3	1	2	2	2	3	3	2	42.00
	ND plus	VISIT 8	3	1	3	1	2	3	2	3	3	2	46.00
	ND plus	VISIT 9	4	1	3	1	2	2	2	5	3	3	52.00
	ND plus	VISIT 10	1	0	1	0	1	1	1	1	1	1	16.00
	ND plus	VISIT 11	0	0	0	0	1	0	0	0	0	0	2.00
06/0615	ND basic	BASELINE (VISIT 2A)	2	2	2	0	2	1	1	1	3	2	32.00
06/0616		BASELINE (VISIT 2A)	2	2	3	2	2	1	2	5	3	1	46.00
06/0617	ND plus	BASELINE (VISIT 2A)	4	2	4	4	4	3	4	4	2	5	72.00
	ND plus	VISIT 3A	3	1	1	2	0	0	2	2	2	2	30.00
06/0618		BASELINE (VISIT 2A)	1	1	2	0	3	0	1	0	0	1	18.00
06/0619	ND basic	BASELINE (VISIT 2A)	3	1	3	2	1	2	1	2	2	2	38.00
	ND basic	VISIT 3A	0	0	4	0	1	0	0	0	0	0	10.00
	ND basic	VISIT 4	2	0	1	0	2	0	1	1	0	0	14.00
	ND basic	VISIT 5	1	0	0	0	1	0	0	0	0	0	4.00
	ND basic	VISIT 6	2	0	2	0	1	1	1	1	0	0	16.00
	ND basic	VISIT 7	1	0	2	0	2	2	1	0	0	0	16.00
	ND basic	VISIT 8	1	0	2	0	1	1	1	2	0	0	16.00
	ND basic	VISIT 9	2	0	2	0	3	3	2	1	2	1	32.00
	ND basic	VISIT 10	3	2	3	0	2	2	2	3	2	2	42.00
	ND basic	VISIT 11	2	2	3	1	2	2	0	3	3	2	40.00
06/0620	SC	BASELINE (VISIT 2A)	2	1	3	1	2	2	1	1	1	2	32.00
	SC	VISIT 4	2	0	2	0	2	1	0	1	0	1	18.00
	SC	VISIT 5	2	0	2	0	2	0	0	0	0	1	14.00
	SC	VISIT 6	1	0	2	0	2	1	0	0	0	2	16.00
	SC	VISIT 7	1	0	2	0	2	1	1	0	1	1	18.00
	SC	VISIT 8	1	0	2	0	2	1	1	0	1	1	18.00
	SC	VISIT 9	2	0	2	0	1	1	1	0	0	1	16.00
	SC	VISIT 10	2	0	1	0	1	0	0	0	0	1	10.00
	SC	VISIT 11	2	0	1	0	1	0	0	0	0	1	10.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
07/0701	ND plus	BASELINE (VISIT 2A)	3	1	3	0	4	2	1	1	4	2	42.00
	ND plus	VISIT 3A	1	0	3	0	2	2	0	1	2	2	26.00
	ND plus	VISIT 4	1	0	3	0	0	0	0	0	0	1	10.00
	ND plus	VISIT 5	0	0	2	0	2	2	0	0	0	1	14.00
	ND plus	VISIT 6	1	0	0	0	1	0	0	0	0	0	4.00
	ND plus	VISIT 7	1	0	0	0	1	0	0	0	0	0	4.00
	ND plus	VISIT 8	1	0	1	0	0	0	0	0	0	0	4.00
	ND plus	VISIT 9	0	0	1	0	1	0	0	0	0	0	4.00
	ND plus	VISIT 10	0	0	1	0	0	0	0	0	0	0	2.00
	ND plus	VISIT 11	1	0	1	0	0	0	0	0	0	1	6.00
07/0702	SC	BASELINE (VISIT 2A)	5	3	5	5	5	5	3	5	4	5	90.00
	SC	VISIT 4	2	1	4	1	2	2	1	3	3	3	44.00
	SC	VISIT 5	2	3	4	1	2	2	1	1	3	2	42.00
	SC	VISIT 6	2	0	3	0	2	1	0	2	2	1	26.00
	SC	VISIT 8	2	0	3	1	2	2	3	1	2	1	34.00
	SC	VISIT 10	3	1	3	1	2	2	3	2	2	2	42.00
07/0703	ND plus	BASELINE (VISIT 2A)	2	1	3	3	2	4	1	5	3	4	56.00
	ND plus	VISIT 3A	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 4	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 5	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 8	1	0	0	0	0	0	0	0	0	0	2.00
	ND plus	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 10	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 11	0	0	0	0	0	0	0	0	0	0	0.00
07/0704	ND basic	BASELINE (VISIT 2A)	2	1	3	1	2	2	1	4	2	3	42.00
	ND basic	VISIT 3A	1	0	0	0	0	0	0	0	0	0	2.00
	ND basic	VISIT 4	1	0	0	0	2	0	0	0	0	0	6.00
	ND basic	VISIT 5	1	0	1	0	2	0	1	0	0	1	12.00
	ND basic	VISIT 6	0	0	0	0	1	0	0	0	0	0	2.00
	ND basic	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 10	1	0	0	0	1	0	0	0	0	0	4.00
	ND basic	VISIT 11	0	0	0	0	0	0	1	0	0	0	2.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
07/0705		BASELINE (VISIT 2A)	2	2	3	3	3	3	1	5	3	3	56.00
07/0706	SC	BASELINE (VISIT 2A)	2	2	4	3	3	4	1	5	4	5	66.00
	SC	VISIT 4	2	2	3	1	2	3	1	4	4	2	48.00
07/0707		BASELINE (VISIT 2A)	4	2	4	3	3	3	2	3	3	4	62.00
08/0801	SC	BASELINE (VISIT 2A)	4	2	3	2	2	2	3	4	4	2	56.00
	SC	VISIT 4	2	0	3	1	2	1	1	3	3	1	34.00
	SC	VISIT 5	2	0	3	1	2	1	1	0	2	2	28.00
	SC	VISIT 6	2	0	2	0	2	1	1	0	2	1	22.00
08/0802	ND plus	BASELINE (VISIT 2A)	2	1	2	1	2	2	1	-	3	1	33.33
	ND plus	VISIT 3A	2	0	2	0	1	1	1	0	2	0	18.00
	ND plus	VISIT 4	1	0	1	0	1	1	1	0	1	0	12.00
	ND plus	VISIT 5	1	0	1	0	0	1	1	0	0	0	8.00
	ND plus	VISIT 6	2	0	2	0	1	1	1	1	0	0	16.00
	ND plus	VISIT 7	2	0	1	0	0	1	1	0	2	0	14.00
	ND plus	VISIT 8	2	0	1	0	1	1	1	2	2	0	20.00
	ND plus	VISIT 9	2	0	2	0	1	1	1	1	2	0	20.00
	ND plus	VISIT 10	2	1	2	0	2	2	1	1	3	1	30.00
	ND plus	VISIT 11	2	0	2	0	1	2	1	1	2	0	22.00
08/0803	ND basic	BASELINE (VISIT 2A)	1	0	2	1	1	1	1	1	1	1	20.00
	ND basic	VISIT 3A	1	0	1	0	0	0	0	0	0	0	4.00
	ND basic	VISIT 4	1	0	1	0	0	0	0	0	0	0	4.00
	ND basic	VISIT 5	0	0	0	0	0	0	0	0	0	0	0.00
08/0804	ND plus	BASELINE (VISIT 2A)	1	1	1	1	3	3	2	1	0	4	34.00
	ND plus	VISIT 3A	0	0	0	0	1	0	0	0	0	0	2.00
	ND plus	VISIT 4	1	0	0	0	0	0	1	0	0	0	4.00
	ND plus	VISIT 5	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 8	2	0	0	0	0	0	0	0	0	0	4.00
	ND plus	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 10	1	0	1	0	1	0	0	0	0	1	8.00
	ND plus	VISIT 11	0	0	0	0	0	0	0	0	0	0	0.00
08/0805	ND basic	BASELINE (VISIT 2A)	2	1	2	1	3	4	2	2	2	2	42.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
08/0805	ND basic	VISIT 3A	1	0	1	0	1	0	0	1	0	1	10.00
	ND basic	VISIT 4	2	0	1	2	2	1	0	1	1	1	22.00
	ND basic	VISIT 5	2	0	1	0	1	0	0	1	0	0	10.00
	ND basic	VISIT 6	1	0	0	0	0	0	0	0	0	0	2.00
	ND basic	VISIT 7	1	0	1	0	1	0	0	0	0	0	6.00
	ND basic	VISIT 8	2	0	1	0	1	1	0	0	0	0	10.00
	ND basic	VISIT 9	2	1	1	1	1	1	1	1	1	1	22.00
	ND basic	VISIT 10	2	0	1	0	1	1	1	0	0	0	12.00
	ND basic	VISIT 11	2	0	1	0	1	1	0	1	0	0	12.00
08/0806	ND plus	BASELINE (VISIT 2A)	1	0	4	1	0	1	1	0	2	0	20.00
	ND plus	VISIT 3A	0	0	2	0	1	2	0	0	2	1	16.00
	ND plus	VISIT 4	0	0	4	0	1	2	0	0	0	0	14.00
	ND plus	VISIT 5	0	0	0	0	1	2	1	0	2	0	12.00
	ND plus	VISIT 6	1	0	1	0	1	2	0	0	0	0	10.00
	ND plus	VISIT 7	0	0	3	0	1	3	1	0	0	0	16.00
	ND plus	VISIT 8	1	0	2	0	1	1	1	0	0	0	12.00
	ND plus	VISIT 9	0	0	1	0	0	1	1	0	0	0	6.00
	ND plus	VISIT 10	1	0	0	0	1	3	1	0	2	0	16.00
	ND plus	VISIT 11	1	0	2	0	1	3	1	0	0	0	16.00
08/0807	ND plus	BASELINE (VISIT 2A)	3	2	4	1	2	4	3	4	3	3	58.00
	ND plus	VISIT 3A	2	1	3	1	3	4	2	0	3	4	46.00
	ND plus	VISIT 4	2	0	2	1	3	1	1	0	3	1	28.00
	ND plus	VISIT 5	0	0	1	0	0	1	0	0	0	0	4.00
	ND plus	VISIT 6	0	0	1	0	0	0	0	0	0	0	2.00
	ND plus	VISIT 7	0	0	1	0	0	0	1	0	0	0	4.00
	ND plus	VISIT 8	2	0	3	0	3	2	1	1	1	1	28.00
08/0808	SC	BASELINE (VISIT 2A)	2	0	3	0	3	3	3	3	2	0	38.00
	SC	VISIT 4	1	0	3	1	2	3	0	-	2	1	28.89
	SC	VISIT 5	1	0	2	0	0	2	0	-	2	0	15.56
	SC	VISIT 6	1	0	2	0	0	2	0	-	0	0	11.11
	SC	VISIT 7	1	0	2	0	0	1	0	0	0	0	8.00
	SC	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 9	1	0	1	0	0	1	0	0	0	0	6.00
	SC	VISIT 10	0	0	0	0	0	0	1	0	0	0	2.00
	SC	VISIT 11	1	0	0	0	0	0	0	0	0	0	2.00
09/0901	SC	BASELINE (VISIT 2A)	3	1	1	0	3	0	1	1	2	3	30.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
09/0901	SC	VISIT 4	2	0	3	0	2	0	1	1	2	1	24.00
	SC	VISIT 5	1	0	1	0	0	0	1	0	0	0	6.00
	SC	VISIT 6	1	0	0	0	0	0	0	0	0	1	4.00
	SC	VISIT 7	1	0	0	0	0	0	0	0	0	0	2.00
	SC	VISIT 8	1	0	0	0	0	0	0	0	0	0	2.00
	SC	VISIT 9	1	0	0	0	0	0	0	0	0	0	2.00
	SC	VISIT 10	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 11	0	0	0	0	0	0	0	0	0	0	0.00
09/0903	ND plus	BASELINE (VISIT 2A)	2	2	4	1	4	1	2	3	4	4	54.00
	ND plus	VISIT 3A	2	0	4	1	4	3	0	3	4	3	48.00
09/0904	ND basic	BASELINE (VISIT 2A)	4	2	3	3	-	-	-	2	3	5	62.86
	ND basic	VISIT 3A	2	1	3	1	2	2	2	1	1	1	32.00
	ND basic	VISIT 4	2	1	1	1	2	1	3	1	1	1	28.00
	ND basic	VISIT 5	2	0	3	1	2	2	3	1	2	2	36.00
	ND basic	VISIT 6	2	0	3	0	2	1	0	1	1	1	22.00
	ND basic	VISIT 7	1	0	1	0	1	1	1	1	1	1	16.00
	ND basic	VISIT 8	1	1	2	0	2	1	3	1	2	1	28.00
	ND basic	VISIT 9	2	1	2	1	2	2	3	1	1	1	32.00
	ND basic	VISIT 10	2	0	2	0	2	2	3	1	0	1	26.00
	ND basic	VISIT 11	2	0	1	1	2	1	0	1	1	1	20.00
09/0905	ND plus	BASELINE (VISIT 2A)	4	0	4	4	3	4	3	3	2	3	60.00
	ND plus	VISIT 3A	1	1	3	1	2	2	1	1	2	2	32.00
	ND plus	VISIT 4	2	1	1	1	2	1	1	1	1	1	24.00
	ND plus	VISIT 5	1	0	2	1	2	2	1	1	0	0	20.00
	ND plus	VISIT 6	1	0	0	0	0	0	1	0	0	0	4.00
	ND plus	VISIT 7	1	0	0	0	1	0	1	0	0	0	6.00
	ND plus	VISIT 8	1	0	1	0	0	1	1	0	0	0	8.00
	ND plus	VISIT 9	-	-	-	1	0	0	1	0	0	0	5.71
	ND plus	VISIT 10	2	1	2	1	2	2	1	1	0	1	26.00
	ND plus	VISIT 11	1	0	0	0	0	1	1	0	0	0	6.00
09/0906		BASELINE (VISIT 2A)	3	1	3	1	2	1	1	1	0	0	26.00
09/0907	SC	BASELINE (VISIT 2A)	1	0	3	1	2	2	1	0	0	0	20.00
	SC	VISIT 4	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 5	0	0	1	0	0	0	0	0	0	0	2.00
	SC	VISIT 6	0	0	0	0	1	0	0	0	0	0	2.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
09/0907	SC	VISIT 7	1	0	0	0	1	0	0	0	0	0	4.00
	SC	VISIT 8	0	0	0	0	1	0	0	0	0	0	2.00
	SC	VISIT 9	0	0	0	0	1	0	0	0	0	0	2.00
	SC	VISIT 10	0	0	0	0	1	0	0	0	0	0	2.00
	SC	VISIT 11	0	0	0	0	1	0	0	0	0	0	2.00
09/0908	ND basic	BASELINE (VISIT 2A)	4	2	2	1	4	4	1	2	2	1	46.00
	ND basic	VISIT 3A	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 4	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 5	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 8	1	0	0	0	0	0	0	0	0	0	2.00
	ND basic	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 10	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 11	0	0	0	0	0	0	0	0	0	0	0.00
09/0909	ND plus	BASELINE (VISIT 2A)	3	3	4	5	4	5	3	5	3	5	80.00
	ND plus	VISIT 3A	0	0	0	0	2	1	0	0	0	1	8.00
	ND plus	VISIT 4	1	0	0	0	1	1	1	0	0	0	8.00
	ND plus	VISIT 5	0	0	1	0	1	1	0	0	0	0	6.00
	ND plus	VISIT 6	0	0	0	0	1	0	1	0	0	0	4.00
	ND plus	VISIT 7	0	0	0	0	1	2	1	0	0	0	8.00
	ND plus	VISIT 8	0	0	0	0	1	1	1	0	0	0	6.00
	ND plus	VISIT 9	0	0	0	0	1	0	0	0	0	0	2.00
	ND plus	VISIT 10	0	0	0	0	1	0	0	0	0	0	2.00
	ND plus	VISIT 11	0	0	0	0	1	1	0	0	0	0	4.00
09/0910	ND plus	BASELINE (VISIT 2A)	5	3	5	5	5	5	4	5	5	5	94.00
09/0911	ND plus	BASELINE (VISIT 2A)	2	1	3	0	3	3	2	0	3	3	40.00
	ND plus	VISIT 3A	2	1	4	1	3	2	1	0	2	3	38.00
	ND plus	VISIT 4	1	0	2	1	3	3	1	0	0	0	22.00
	ND plus	VISIT 5	1	0	1	1	2	2	1	0	0	0	16.00
	ND plus	VISIT 6	1	0	4	1	2	2	0	0	2	0	24.00
	ND plus	VISIT 7	1	0	2	0	2	2	1	0	0	0	16.00
	ND plus	VISIT 8	1	0	1	0	2	2	1	0	0	0	14.00
	ND plus	VISIT 9	2	0	1	0	1	0	0	0	0	0	8.00
	ND plus	VISIT 10	2	0	3	1	3	3	1	0	0	0	26.00
	ND plus	VISIT 11	0	0	3	0	1	2	0	0	0	0	12.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
09/0912	ND plus	BASELINE (VISIT 2A)	3	2	3	1	3	2	1	3	3	4	50.00
	ND plus	VISIT 3A	1	0	1	0	2	1	0	0	0	0	10.00
	ND plus	VISIT 4	1	0	0	0	0	0	1	0	0	0	4.00
	ND plus	VISIT 5	0	0	1	0	1	0	0	0	0	0	4.00
	ND plus	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 7	0	0	0	0	1	0	0	0	0	0	2.00
	ND plus	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 9	0	0	1	0	1	0	0	0	0	0	4.00
	ND plus	VISIT 10	0	0	1	0	1	0	0	0	0	0	4.00
	ND plus	VISIT 11	0	0	0	0	1	0	0	0	0	0	2.00
09/0913	ND basic	BASELINE (VISIT 2A)	3	2	3	0	0	2	2	4	2	1	38.00
	ND basic	VISIT 3A	1	0	1	0	2	1	0	-	0	0	11.11
	ND basic	VISIT 4	1	0	1	0	0	1	0	0	0	0	6.00
	ND basic	VISIT 5	2	0	1	0	0	1	0	-	0	0	8.89
	ND basic	VISIT 6	0	0	0	0	0	1	0	0	0	0	2.00
	ND basic	VISIT 7	2	0	1	0	0	0	0	0	0	0	6.00
	ND basic	VISIT 8	1	0	0	0	0	1	0	0	0	0	4.00
	ND basic	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 10	1	0	0	0	1	1	0	0	0	0	6.00
	ND basic	VISIT 11	0	0	0	0	0	0	0	0	0	0	0.00
09/0914	SC	BASELINE (VISIT 2A)	4	2	3	2	3	2	3	3	3	3	56.00
	SC	VISIT 4	1	2	3	0	2	1	0	3	2	1	30.00
	SC	VISIT 5	1	1	2	0	3	1	0	1	0	1	20.00
	SC	VISIT 6	1	0	2	0	2	1	1	0	0	1	16.00
	SC	VISIT 7	0	0	1	0	1	1	0	0	0	0	6.00
	SC	VISIT 8	3	2	1	0	2	0	1	0	0	0	18.00
	SC	VISIT 9	2	0	2	0	2	1	0	1	2	0	20.00
	SC	VISIT 10	2	0	1	0	2	1	0	0	1	0	14.00
	SC	VISIT 11	1	0	2	0	2	0	0	0	0	0	10.00
09/0915	ND basic	BASELINE (VISIT 2A)	4	1	3	0	4	2	2	1	2	1	40.00
	ND basic	VISIT 3A	0	0	0	0	0	0	1	0	0	0	2.00
	ND basic	VISIT 4	0	0	0	0	0	0	1	0	0	0	2.00
	ND basic	VISIT 5	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 7	0	0	0	0	0	0	1	0	0	0	2.00
	ND basic	VISIT 8	1	0	0	0	0	0	1	0	0	0	4.00
	ND basic	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
09/0915	ND basic	VISIT 10	2	0	1	0	3	0	2	0	0	0	16.00
	ND basic	VISIT 11	0	0	0	0	1	0	1	0	0	0	4.00
09/0916	SC	BASELINE (VISIT 2A)	4	2	4	3	5	5	1	3	3	4	68.00
	SC	VISIT 4	2	0	2	0	0	0	0	0	0	0	8.00
	SC	VISIT 5	2	0	4	3	2	3	0	0	0	1	30.00
	SC	VISIT 6	2	0	3	1	0	3	0	0	0	0	18.00
	SC	VISIT 7	1	0	2	0	0	4	0	0	0	0	14.00
	SC	VISIT 8	1	0	2	0	1	3	0	0	0	1	16.00
	SC	VISIT 9	2	0	3	0	2	3	0	0	0	0	20.00
	SC	VISIT 10	2	0	2	0	2	3	0	0	0	0	18.00
10/1001		VISIT 11	1	0	2	0	2	4	1	0	0	1	22.00
		BASELINE (VISIT 2A)	4	3	4	3	4	4	4	5	4	3	76.00
11/1101	ND plus	BASELINE (VISIT 2A)	2	1	4	1	3	3	2	4	4	3	54.00
	ND plus	VISIT 3A	1	0	4	1	2	1	0	0	1	1	22.00
	ND plus	VISIT 4	1	0	1	0	1	1	0	0	0	1	10.00
	ND plus	VISIT 5	0	0	1	0	0	0	0	0	0	0	2.00
	ND plus	VISIT 6	2	1	1	1	2	1	1	1	1	1	24.00
	ND plus	VISIT 7	1	0	1	1	1	1	1	0	0	1	14.00
	ND plus	VISIT 8	3	1	1	1	2	2	1	0	1	2	28.00
	ND plus	VISIT 9	2	0	3	1	2	2	1	1	1	1	28.00
	ND plus	VISIT 10	3	2	3	1	3	2	1	1	3	2	42.00
11/1102	ND plus	VISIT 11	4	2	3	1	4	4	2	5	4	3	64.00
	ND basic	BASELINE (VISIT 2A)	4	2	3	5	5	5	1	5	4	5	78.00
	ND basic	VISIT 3A	0	0	0	0	1	0	0	0	0	0	2.00
	ND basic	VISIT 4	0	0	1	0	0	0	0	0	0	0	2.00
	ND basic	VISIT 5	1	0	1	0	0	0	0	0	0	0	4.00
	ND basic	VISIT 6	1	0	1	0	1	0	0	0	0	0	6.00
	ND basic	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 8	0	0	0	0	0	1	0	0	0	0	2.00
	ND basic	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
11/1103	ND basic	VISIT 10	1	0	0	0	0	0	0	0	0	0	2.00
	ND basic	VISIT 11	0	0	0	0	1	0	0	0	0	0	2.00
	SC	BASELINE (VISIT 2A)	3	2	4	5	5	5	2	4	5	5	80.00
11/1103	SC	VISIT 4	2	1	1	0	2	3	1	-	3	3	35.56
	SC	VISIT 5	1	1	1	1	2	1	1	-	2	1	24.44

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
11/1103	SC	VISIT 6	0	0	1	1	2	2	1	-	1	1	20.00
	SC	VISIT 7	2	0	1	1	2	2	1	0	0	1	20.00
	SC	VISIT 8	1	0	1	1	2	2	1	1	1	1	22.00
	SC	VISIT 9	3	2	4	1	3	3	1	4	3	3	54.00
	SC	VISIT 10	3	1	4	1	2	4	1	1	3	1	42.00
	SC	VISIT 11	2	1	2	1	3	4	1	1	3	1	38.00
11/1104	ND plus	BASELINE (VISIT 2A)	2	0	0	0	2	0	1	0	0	0	10.00
	ND plus	VISIT 3A	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 4	0	0	0	1	0	0	0	0	0	0	2.00
	ND plus	VISIT 5	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
	ND plus	VISIT 10	0	0	0	0	1	0	0	0	0	0	2.00
	ND plus	VISIT 11	0	0	0	0	0	0	0	0	0	0	0.00
12/1201	ND plus	BASELINE (VISIT 2A)	3	1	5	3	5	4	0	5	4	5	70.00
	ND plus	VISIT 3A	0	0	4	1	2	3	0	4	2	0	32.00
	ND plus	VISIT 4	4	0	3	0	2	2	1	-	2	-	35.00
	ND plus	VISIT 5	2	0	2	0	2	4	1	-	0	-	27.50
	ND plus	VISIT 6	3	2	4	0	3	4	3	-	1	4	53.33
	ND plus	VISIT 7	2	1	2	1	1	1	1	-	2	3	31.11
	ND plus	VISIT 8	2	0	3	1	2	3	1	-	3	3	40.00
	ND plus	VISIT 9	4	2	4	1	3	4	3	-	3	3	60.00
	ND plus	VISIT 10	4	0	3	1	1	3	2	-	3	-	42.50
	ND plus	VISIT 11	2	0	3	0	1	3	1	-	0	1	24.44
13/1301	ND plus	BASELINE (VISIT 2A)	3	2	3	2	4	3	1	5	2	3	56.00
	ND plus	VISIT 3A	0	0	4	0	2	1	1	-	0	2	22.22
	ND plus	VISIT 4	1	1	3	0	2	1	1	0	0	1	20.00
	ND plus	VISIT 5	1	0	1	0	2	0	1	0	2	2	18.00
	ND plus	VISIT 6	2	0	2	0	2	0	1	0	2	1	20.00
	ND plus	VISIT 7	1	0	3	0	2	0	1	0	0	1	16.00
	ND plus	VISIT 8	1	0	3	0	2	0	1	1	0	1	18.00
	ND plus	VISIT 9	2	0	3	0	2	1	1	1	1	1	24.00
	ND plus	VISIT 10	2	0	3	1	2	2	1	-	2	1	31.11
	ND plus	VISIT 11	1	0	3	0	2	1	1	1	0	1	20.00

Listing 16.2.2.1: Oswestry Disability Questionnaire - all enrolled subjects

Site/ SubjectID	Treatment group	Visit	Pain	Personal care	Lifting	Walking	Sitting	Standing	Sleeping	Sexual Life	Social Life	Travelling	ODI total score
13/1302	ND plus	BASELINE (VISIT 2A)	3	2	3	3	4	4	2	4	4	5	68.00
	ND plus	VISIT 3A	1	0	3	0	2	1	0	0	0	1	16.00
	ND plus	VISIT 4	1	0	1	0	1	0	0	0	0	1	8.00
	ND plus	VISIT 5	0	0	1	0	0	0	0	0	0	1	4.00
	ND plus	VISIT 6	1	0	1	0	0	0	0	0	0	0	4.00
	ND plus	VISIT 7	0	0	1	0	0	0	1	0	0	0	4.00
	ND plus	VISIT 8	1	0	1	0	0	0	1	0	0	1	8.00
	ND plus	VISIT 9	1	0	0	0	1	0	1	0	0	1	8.00
	ND plus	VISIT 10	1	0	1	0	1	0	1	0	0	1	10.00
	ND plus	VISIT 11	1	0	1	0	0	0	1	0	0	1	8.00
13/1303	SC	BASELINE (VISIT 2A)	2	1	1	0	2	0	1	0	2	3	24.00
	SC	VISIT 4	0	0	1	0	2	0	0	0	0	1	8.00
	SC	VISIT 5	0	0	2	0	2	0	0	0	0	1	10.00
	SC	VISIT 6	0	0	0	0	1	0	0	0	0	0	2.00
	SC	VISIT 7	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 8	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 9	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 10	0	0	0	0	0	0	0	0	0	0	0.00
	SC	VISIT 11	2	1	0	0	1	0	0	0	0	0	8.00
13/1304	ND basic	BASELINE (VISIT 2A)	3	2	0	2	3	4	2	4	4	5	58.00
	ND basic	VISIT 3A	1	0	1	0	0	1	0	1	3	0	14.00
	ND basic	VISIT 4	1	0	0	0	0	0	0	0	2	0	6.00
	ND basic	VISIT 5	1	0	0	0	0	0	0	0	0	0	2.00
	ND basic	VISIT 6	0	0	0	0	0	0	0	0	0	0	0.00
	ND basic	VISIT 7	2	0	0	0	0	1	0	0	0	0	6.00
	ND basic	VISIT 8	1	0	0	0	0	1	0	0	0	0	4.00
	ND basic	VISIT 9	1	0	0	0	1	0	0	0	0	0	4.00
	ND basic	VISIT 10	0	0	0	0	1	0	0	0	0	0	2.00
	ND basic	VISIT 11	0	0	0	0	0	0	0	0	0	0	0.00
13/1305	ND plus	BASELINE (VISIT 2A)	3	2	5	0	3	3	3	5	3	5	64.00

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
01/0103	ND basic	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	17OCT2012	3.9	0.2	7.5
	ND basic	ES/SAF/FAS	Right	VISIT 3A	14JAN2013	2.1	0	4.4
	ND basic	ES/SAF/FAS	Right	VISIT 4	20FEB2013	3.4	1.1	4.1
	ND basic	ES/SAF/FAS	Right	VISIT 5	17APR2013	5.6	0.4	5.6
	ND basic	ES/SAF/FAS	Right	VISIT 6	18JUL2013	6.9	1.3	7.6
	ND basic	ES/SAF/FAS	Right	VISIT 7	08JAN2014	5.5	1.2	6.8
	ND basic	ES/SAF/FAS	Right	VISIT 8	16FEB2015	7.5	1.5	7.7
	ND basic	ES/SAF/FAS	Right	VISIT 11	17JAN2018	6.9	0	3.5
01/0104	ND basic	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	23OCT2012	2.2	0	3.5
	ND basic	ES/SAF/FAS	Right	VISIT 3A	21JAN2013	0	0	0
	ND basic	ES/SAF/FAS	Right	VISIT 4	27FEB2013	0	0	0
	ND basic	ES/SAF/FAS	Right	VISIT 5	26APR2013	0	0	0
	ND basic	ES/SAF/FAS	Right	VISIT 6	31JUL2013	3.4	0	2
	ND basic	ES/SAF/FAS	Right	VISIT 7	15JAN2014	0	0	0
	ND basic	ES/SAF/FAS	Right	VISIT 8	23JUN2015	0	1.4	0
	ND basic	ES/SAF/FAS	Right	VISIT 11	24JAN2018	0.1	0.1	0.2
01/0106	ND plus	ES/SAF/FAS	Right	VISIT 3A	18FEB2013	0.2	0.3	1.1
	ND plus	ES/SAF/FAS	Right	VISIT 4	03APR2013	0.1	0.2	0.1
	ND plus	ES/SAF/FAS	Right	VISIT 5	22MAY2013	0.4	0.6	0.9
	ND plus	ES/SAF/FAS	Right	VISIT 6	21AUG2013	1.2	0.1	0.1
	ND plus	ES/SAF/FAS	Right	VISIT 7	19FEB2014	1.5	1.2	1.1
	ND plus	ES/SAF/FAS	Right	VISIT 8	18FEB2015	3.2	1	0.9
	ND plus	ES/SAF/FAS	Right	VISIT 11	14FEB2018	0.2	0.2	0.2
01/0107	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	08JAN2013	0	0	2.6
	ND plus	ES/SAF/FAS	Right	VISIT 3A	08APR2013	0.2	0.1	0.1
	ND plus	ES/SAF/FAS	Right	VISIT 4	15MAY2013	0	0	0.3
	ND plus	ES/SAF/FAS	Right	VISIT 5	03JUL2013	1.4	0	0
	ND plus	ES/SAF/FAS	Right	VISIT 6	25SEP2013	0.9	0	0
	ND plus	ES/SAF/FAS	Right	VISIT 7	26MAR2014	0.8	0	0.9
	ND plus	ES/SAF/FAS	Right	VISIT 8	08APR2015	0.1	0.1	0.5
	ND plus	ES/SAF/FAS	Right	VISIT 11	11APR2018	1	0.2	0.2
01/0108	ND plus	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	09JAN2013	0	0.4	0
	ND plus	ES/SAF/FAS	Left	VISIT 3A	15APR2013	0.6	0	0
	ND plus	ES/SAF/FAS	Left	VISIT 4	29MAY2013	0.1	0.1	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 5	11JUL2013	0	0	0.8
	ND plus	ES/SAF/FAS	Left	VISIT 6	01OCT2013	0.6	0	0.4
	ND plus	ES/SAF/FAS	Left	VISIT 7	02APR2014	2.6	0	0

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
01/0108	ND plus	ES/SAF/FAS	Left	VISIT 8	16APR2015	1.1	0.2	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 11	21MAR2018	0.1	0.1	0
01/0110	ND basic	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	23JAN2013	2.3	0	5.4
	ND basic	ES/SAF/FAS	Right	VISIT 3A	22APR2013	1.3	0.1	1.1
	ND basic	ES/SAF/FAS	Right	VISIT 4	05JUN2013	0.6	0.5	0.4
	ND basic	ES/SAF/FAS	Right	VISIT 5	31JUL2013	0	0	0
	ND basic	ES/SAF/FAS	Right	VISIT 6	15OCT2013	0.2	0	0
	ND basic	ES/SAF/FAS	Right	VISIT 7	09APR2014	0.5	0.1	0.3
	ND basic	ES/SAF/FAS	Right	VISIT 8	22APR2015	1.1	0.1	0.2
	ND basic	ES/SAF/FAS	Right	VISIT 11	28MAR2018	2.8	2.7	2.3
01/0111	ND plus	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	11MAR2013	2.1	5.4	0
	ND plus	ES/SAF/FAS	Left	VISIT 3A	10JUN2013	0.3	1.1	0
	ND plus	ES/SAF/FAS	Left	VISIT 4	25JUL2013	0.5	0.6	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 5	04SEP2013	0.3	0.1	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 6	18DEC2013	1	0.1	0
	ND plus	ES/SAF/FAS	Left	VISIT 7	04JUN2014	0.1	0.1	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 8	10JUN2015	0.1	0.1	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 11	30MAY2018	0	0	0
01/0112	ND basic	ES/SAF	Right	BASELINE (VISIT 2A)	26MAR2013	5	0.1	7.4
	ND basic	ES/SAF	Right	VISIT 11	08JUL2013	1.6	0	1.7
01/0113	ND basic	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	22MAY2013	0.2	5.2	0.2
	ND basic	ES/SAF/FAS	Left	VISIT 3A	05AUG2013	0.1	0	0
	ND basic	ES/SAF/FAS	Left	UNSCHEDULED	28AUG2013	0	0	0
	ND basic	ES/SAF/FAS	Left	VISIT 4	10SEP2013	0	0	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 5	06NOV2013	0	1.2	0
	ND basic	ES/SAF/FAS	Left	VISIT 6	28JAN2014	0.1	0.1	0.1
	ND basic	ES/SAF/FAS	Left	UNSCHEDULED	11JUL2014	0.1	2.7	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 7	30JUL2014	0.2	3.5	0.2
	ND basic	ES/SAF/FAS	Left	UNSCHEDULED	03SEP2014	5.6	0.2	0.2
	ND basic	ES/SAF/FAS	Left	UNSCHEDULED	02OCT2014	8.1	0.3	0.2
	ND basic	ES/SAF/FAS	Left	VISIT 8	22JUL2015	0	0.1	0
	ND basic	ES/SAF/FAS	Left	VISIT 11	17OCT2018	0.1	0	0.1
01/0114	ND basic	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	10JUN2013	8.5	8.5	0.3
	ND basic	ES/SAF/FAS	Left	VISIT 3A	10SEP2013	2.4	0.8	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 4	16OCT2013	0.1	0.1	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 5	10DEC2013	0.1	0.1	0.1

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
01/0114	ND basic	ES/SAF/FAS	Left	VISIT 6	12MAR2014	0.1	0.1	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 7	10SEP2014	0	0	0
	ND basic	ES/SAF/FAS	Left	VISIT 8	09SEP2015	0	0	0
	ND basic	ES/SAF/FAS	Left	VISIT 11	05SEP2018	0.2	0.1	0.2
01/0115	ND plus	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	11JUN2013	1.1	7.1	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 3A	16SEP2013	1.5	0.1	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 4	30OCT2013	0.7	0	0
	ND plus	ES/SAF/FAS	Left	VISIT 5	12DEC2013	2.3	0	0
	ND plus	ES/SAF/FAS	Left	VISIT 6	11MAR2014	2	0	0
	ND plus	ES/SAF/FAS	Left	VISIT 7	25SEP2014	1.4	0	0
	ND plus	ES/SAF/FAS	Left	VISIT 8	16SEP2015	1.1	0.1	0
01/0116	ND plus	ES/SAF/FAS	Left	VISIT 11	10OCT2018	0.4	0.4	0.6
	ND basic	ES/SAF	Right	BASELINE (VISIT 2A)	17JUN2013	1.9	0	1.9
01/0118	ND plus	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	09JUL2013	3.3	4.1	0
	ND plus	ES/SAF/FAS	Left	VISIT 3A	07OCT2013	2.3	5	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 4	20NOV2013	2.2	8.6	0.4
	ND plus	ES/SAF/FAS	Left	VISIT 5	07JAN2014	2.1	6.8	0
	ND plus	ES/SAF/FAS	Left	VISIT 6	25MAR2014	0.9	6.2	0
	ND plus	ES/SAF/FAS	Left	UNSCHEDULED	09JUL2014	2.6	4.1	0
	ND plus	ES/SAF/FAS	Left	UNSCHEDULED	18SEP2014	2.5	9.5	0
	ND plus	ES/SAF/FAS	Left	VISIT 7	08OCT2014	1.5	7.9	0.1
	ND plus	ES/SAF/FAS	Left	UNSCHEDULED	22OCT2014	2	6	0
	ND plus	ES/SAF/FAS	Left	VISIT 8	07OCT2015	3.9	7.4	0.1
	ND plus	ES/SAF/FAS	Left	UNSCHEDULED	15JUN2016	4.4	7.8	0.1
	ND plus	ES/SAF/FAS	Left	UNSCHEDULED				
01/0119	ND basic	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	22JUL2013	0.1	0.1	0
	ND basic	ES/SAF/FAS	Left	VISIT 3A	14OCT2013	0.9	0.7	0
	ND basic	ES/SAF/FAS	Left	VISIT 4	19NOV2013	0	0.4	0
	ND basic	ES/SAF/FAS	Left	VISIT 5	14JAN2014	0	0	0
	ND basic	ES/SAF/FAS	Left	VISIT 6	03APR2014	0	0.4	0
	ND basic	ES/SAF/FAS	Left	UNSCHEDULED	14JUL2014	8.9	0	0
	ND basic	ES/SAF/FAS	Left	VISIT 7	15OCT2014	2.5	1.9	0
	ND basic	ES/SAF/FAS	Left	VISIT 8	14OCT2015	0	0	0
	ND basic	ES/SAF/FAS	Left	VISIT 11	10OCT2018	3.4	2.5	0
	ND basic	ES/SAF/FAS	Left	UNSCHEDULED				
01/0121	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	14OCT2013	5.4	0	5
	ND plus	ES/SAF/FAS	Right	VISIT 3A	13JAN2014	0	0	0
	ND plus	ES/SAF/FAS	Right	VISIT 4	18FEB2014	0	1.5	0.4

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
01/0121	ND plus	ES/SAF/FAS	Right	VISIT 5	08APR2014	0	0.1	0
	ND plus	ES/SAF/FAS	Right	VISIT 6	14JUL2014	0	0.1	0
	ND plus	ES/SAF/FAS	Right	VISIT 7	21JAN2015	0	0	0
	ND plus	ES/SAF/FAS	Right	VISIT 8	13JAN2016	0.1	0.2	0.1
01/0122	ND plus	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	25SEP2013	0	5.9	0
	ND plus	ES/SAF/FAS	Left	VISIT 3A	16DEC2013	0	0	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 4	29JAN2014	0	0	0
	ND plus	ES/SAF/FAS	Left	VISIT 5	18MAR2014	0	0	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 6	11JUN2014	0	0	0
	ND plus	ES/SAF/FAS	Left	VISIT 7	17DEC2014	1.6	1.5	0
	ND plus	ES/SAF/FAS	Left	VISIT 8	16DEC2015	0	0	0.1
	ND plus	ES/SAF/FAS	Left	UNSCHEDULED	15JUN2016	5.9	0.2	5.7
01/0123	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	15SEP2014	6.2	0.6	6.9
	ND plus	ES/SAF/FAS	Right	VISIT 3A	18DEC2014	3.1	1.2	5.4
	ND plus	ES/SAF/FAS	Right	VISIT 4	28JAN2015	6	0.1	6.4
	ND plus	ES/SAF/FAS	Right	VISIT 5	20MAR2015	6.5	0	6.4
	ND plus	ES/SAF/FAS	Right	VISIT 6	02JUL2015	5.3	0.1	5.9
	ND plus	ES/SAF/FAS	Right	VISIT 7	17DEC2015	3.9	-	3.9
	ND plus	ES/SAF/FAS	Right	VISIT 8	07DEC2016	5.6	4.4	6.8
01/0124	ND plus	ES/SAF	Right	BASELINE (VISIT 2A)	05NOV2014	3	0	5.7
01/0125	SC	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	06OCT2014	3.4	4.4	0.2
	SC	ES/SAF/FAS	Left	VISIT 4	19NOV2014	0.9	0.3	0.3
	SC	ES/SAF/FAS	Left	VISIT 5	07JAN2015	0.5	0	0.1
	SC	ES/SAF/FAS	Left	VISIT 6	25MAR2015	0.2	0.1	0.1
	SC	ES/SAF/FAS	Left	VISIT 7	30SEP2015	0.3	0.2	0.2
	SC	ES/SAF/FAS	Left	VISIT 8	28SEP2016	1.6	0.2	0.2
	SC	ES/SAF/FAS	Left	VISIT 11	02OCT2019	2.2	0.2	0.1
01/0126	ND basic	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	07OCT2014	7.3	9.9	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 3A	07JAN2015	2.8	0.9	0
	ND basic	ES/SAF/FAS	Left	VISIT 4	16FEB2015	3	3	0
	ND basic	ES/SAF/FAS	Left	VISIT 5	08APR2015	1.8	0.8	0
	ND basic	ES/SAF/FAS	Left	VISIT 6	30JUN2015	1.5	0	0
	ND basic	ES/SAF/FAS	Left	VISIT 7	12JAN2016	1.1	0.6	0.5
	ND basic	ES/SAF/FAS	Left	VISIT 8	11JAN2017	0	0	0
	ND basic	ES/SAF/FAS	Left	VISIT 11	11DEC2019	2	0.1	0.1

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
01/0127	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	20OCT2014	0.6	0	5.3
	ND plus	ES/SAF/FAS	Right	VISIT 3A	08JAN2015	0.2	0.2	0.4
	ND plus	ES/SAF/FAS	Right	VISIT 4	19FEB2015	1.2	0	1.1
	ND plus	ES/SAF/FAS	Right	VISIT 5	08APR2015	0.3	0	0.9
	ND plus	ES/SAF/FAS	Right	VISIT 6	01JUL2015	0.3	0	1.9
	ND plus	ES/SAF/FAS	Right	VISIT 7	13JAN2016	0.1	0.1	0.7
	ND plus	ES/SAF/FAS	Right	VISIT 8	11JAN2017	0.1	0.1	2.3
	ND plus	ES/SAF/FAS	Right	VISIT 11	18DEC2019	1.4	0.1	0.1
01/0128	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	21OCT2014	5.2	0.9	8.2
	ND plus	ES/SAF/FAS	Right	VISIT 3A	12JAN2015	1.5	0	1
	ND plus	ES/SAF/FAS	Right	VISIT 4	24FEB2015	1	0.1	1
	ND plus	ES/SAF/FAS	Right	VISIT 5	14APR2015	0	0	0
	ND plus	ES/SAF/FAS	Right	VISIT 6	14JUL2015	0.3	0	0
	ND plus	ES/SAF/FAS	Right	VISIT 7	14JAN2016	1.6	0.1	0
	ND plus	ES/SAF/FAS	Right	VISIT 8	25JAN2017	0.5	0.1	0.1
	ND plus	ES/SAF/FAS	Right	VISIT 11	18DEC2019	2.8	0.2	3.9
01/0129	SC	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	28OCT2014	6.4	0.1	6.6
	SC	ES/SAF/FAS	Right	VISIT 4	10DEC2014	0	0	3.4
	SC	ES/SAF/FAS	Right	VISIT 5	21JAN2015	0	0	0.6
	SC	ES/SAF/FAS	Right	VISIT 6	14APR2015	0	1.5	0
	SC	ES/SAF/FAS	Right	VISIT 7	21OCT2015	0.5	-	0.9
	SC	ES/SAF/FAS	Right	VISIT 8	05OCT2016	0.1	0.1	0.7
	SC	ES/SAF/FAS	Right	VISIT 11	02OCT2019	0.1	0	0
01/0130	ND basic	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	19NOV2014	2.4	6.9	0
	ND basic	ES/SAF/FAS	Left	VISIT 3A	02FEB2015	1.6	1.8	0.2
	ND basic	ES/SAF/FAS	Left	VISIT 4	17MAR2015	0.1	0	0
	ND basic	ES/SAF/FAS	Left	VISIT 5	27APR2015	0.7	0.2	0.2
	ND basic	ES/SAF/FAS	Left	VISIT 6	29JUL2015	1.3	0.3	0.2
	ND basic	ES/SAF/FAS	Left	VISIT 7	20JAN2016	0.5	0.6	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 8	01FEB2017	0.7	1	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 11	22JAN2020	1.2	0.1	0.1
01/0131	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	30NOV2014	2.2	0.1	4.5
	ND plus	ES/SAF/FAS	Right	VISIT 3A	18FEB2015	0.8	0.2	0.3
	ND plus	ES/SAF/FAS	Right	VISIT 4	09APR2015	0.3	0.3	0.2
	ND plus	ES/SAF/FAS	Right	VISIT 5	27MAY2015	0.2	0.1	0.1
	ND plus	ES/SAF/FAS	Right	VISIT 6	18AUG2015	1	0.2	0.5
	ND plus	ES/SAF/FAS	Right	VISIT 7	18FEB2016	0.4	0.3	0.3

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
01/0131	ND plus	ES/SAF/FAS	Right	VISIT 8	15MAR2017	1.9	0.1	0.1
	ND plus	ES/SAF/FAS	Right	VISIT 11	29JAN2020	0.3	0.1	0.2
01/0132	SC	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	01DEC2014	3.1	5.5	0.3
	SC	ES/SAF/FAS	Left	VISIT 4	13JAN2015	0.2	0.3	0.4
	SC	ES/SAF/FAS	Left	VISIT 5	18MAR2015	0.1	0	0.1
	SC	ES/SAF/FAS	Left	VISIT 6	20MAY2015	1.7	0.2	0.2
	SC	ES/SAF/FAS	Left	VISIT 7	25NOV2015	0.2	0.3	0.3
	SC	ES/SAF/FAS	Left	VISIT 8	23NOV2016	0.4	0.4	0.4
	SC	ES/SAF/FAS	Left	VISIT 11	20NOV2019	1.4	0.2	0.2
01/0133	ND plus	ES/SAF	Left	BASELINE (VISIT 2A)	15DEC2014	4.9	8.3	2.5
01/0134	ND basic	ES/SAF	Left	BASELINE (VISIT 2A)	16DEC2014	2.2	7.3	0.4
01/0135	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	14JAN2015	1.3	0.3	3.9
	ND plus	ES/SAF/FAS	Right	VISIT 3A	07APR2015	1.8	0.2	0.3
	ND plus	ES/SAF/FAS	Right	VISIT 4	26MAY2015	1.1	0.3	0.3
	ND plus	ES/SAF/FAS	Right	VISIT 5	07JUL2015	0.4	0.5	0.5
	ND plus	ES/SAF/FAS	Right	VISIT 6	06OCT2015	2.8	0.6	0.6
	ND plus	ES/SAF/FAS	Right	VISIT 7	06APR2016	2	0.8	1
	ND plus	ES/SAF/FAS	Right	VISIT 8	03MAY2017	0.9	0.3	0.7
	ND plus	ES/SAF/FAS	Right	VISIT 11	27MAY2020	2.8	1.6	1.7
01/0136	ND basic	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	23FEB2015	2.1	0	3.9
	ND basic	ES/SAF/FAS	Right	VISIT 3A	01JUN2015	1	0	3
	ND basic	ES/SAF/FAS	Right	VISIT 4	15JUL2015	0.4	0	2
	ND basic	ES/SAF/FAS	Right	VISIT 5	26AUG2015	0.2	0.1	2.8
	ND basic	ES/SAF/FAS	Right	VISIT 6	24NOV2015	1.2	0	7.2
	ND basic	ES/SAF/FAS	Right	VISIT 7	25MAY2016	0.1	0.1	8.3
	ND basic	ES/SAF/FAS	Right	VISIT 8	06JUN2017	8.3	0.1	9.2
	ND basic	ES/SAF/FAS	Right	VISIT 11	10JUN2020	3.9	0.1	8.2
01/0137	ND plus	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	25FEB2015	0.1	1	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 3A	01JUN2015	0	0	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 4	16JUL2015	0.8	0	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 5	25AUG2015	1.8	0	0
	ND plus	ES/SAF/FAS	Left	VISIT 6	18NOV2015	0.7	0	0
	ND plus	ES/SAF/FAS	Left	VISIT 7	01JUN2016	0.5	0	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 8	07JUN2017	0.2	0.1	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 11	24JUN2020	0.6	0.1	1

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
01/0138	SC	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	08MAR2015	0.2	0.2	1.2
	SC	ES/SAF/FAS	Right	VISIT 4	23APR2015	0.2	0.2	0.2
	SC	ES/SAF/FAS	Right	VISIT 5	05JUN2015	0.2	0.1	0.7
	SC	ES/SAF/FAS	Right	VISIT 6	15SEP2015	0.2	0.3	0.3
	SC	ES/SAF/FAS	Right	VISIT 7	24FEB2016	0.3	0.2	0.2
	SC	ES/SAF/FAS	Right	VISIT 8	08FEB2017	0.3	0.3	0.4
	SC	ES/SAF/FAS	Right	VISIT 11	12FEB2020	0.2	0.3	0.2
01/0139	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	09MAR2015	7.1	0.8	7.4
	ND plus	ES/SAF/FAS	Right	VISIT 3A	02JUN2015	0.5	0	0.3
	ND plus	ES/SAF/FAS	Right	VISIT 4	14JUL2015	0.2	0	1
	ND plus	ES/SAF/FAS	Right	VISIT 5	26AUG2015	1.3	0	1
	ND plus	ES/SAF/FAS	Right	VISIT 6	02DEC2015	0.5	0	2.4
	ND plus	ES/SAF/FAS	Right	VISIT 7	15JUN2016	0.4	0.2	1.4
	ND plus	ES/SAF/FAS	Right	VISIT 8	07JUN2017	1.6	4	1.6
01/0140	ND basic	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	11MAY2015	5.7	-	6.6
	ND basic	ES/SAF/FAS	Right	VISIT 3A	10AUG2015	1.2	0.5	0
	ND basic	ES/SAF/FAS	Right	VISIT 4	22SEP2015	1.7	1.1	0.9
	ND basic	ES/SAF/FAS	Right	VISIT 5	04NOV2015	0.9	0.7	0.7
	ND basic	ES/SAF/FAS	Right	VISIT 6	08FEB2016	2.6	0.8	1.1
	ND basic	ES/SAF/FAS	Right	VISIT 7	27JUL2016	1.3	0.2	0.3
	ND basic	ES/SAF/FAS	Right	VISIT 8	26JUL2017	1.6	1.1	1.1
01/0141	ND basic	ES/SAF/FAS	Right	VISIT 11	19AUG2020	8.9	8.5	9.4
	SC	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	26MAY2015	0.2	0.2	9.4
	SC	ES/SAF/FAS	Right	VISIT 4	13JUL2015	0.9	0	1.8
	SC	ES/SAF/FAS	Right	VISIT 5	02SEP2015	2.1	0.1	1.3
	SC	ES/SAF/FAS	Right	VISIT 6	11NOV2015	1	0	0.5
	SC	ES/SAF/FAS	Right	VISIT 7	18MAY2016	1.4	0.2	0.6
	SC	ES/SAF/FAS	Right	VISIT 11	24JUN2020	0.3	1.1	1.2
01/0142	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	26MAY2015	2.4	0	0.6
	ND plus	ES/SAF/FAS	Right	VISIT 3A	24AUG2015	1	-	0.2
	ND plus	ES/SAF/FAS	Right	VISIT 4	05OCT2015	0.5	0.2	0
	ND plus	ES/SAF/FAS	Right	VISIT 5	25NOV2015	2.4	0.1	0.1
	ND plus	ES/SAF/FAS	Right	VISIT 6	02MAR2016	1.6	0.1	0
	ND plus	ES/SAF/FAS	Right	VISIT 7	31AUG2016	1.8	0	0
	ND plus	ES/SAF/FAS	Right	VISIT 8	30AUG2017	0.8	0.1	0.1
01/0142	ND plus	ES/SAF/FAS	Right	VISIT 11	05AUG2020	1.6	-	1.9

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
01/0143	ND plus	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	16JUN2015	2.4	2.1	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 3A	21SEP2015	0.7	0.1	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 4	02NOV2015	1.8	0.3	1
	ND plus	ES/SAF/FAS	Left	VISIT 5	16DEC2015	1.3	0.1	0.3
	ND plus	ES/SAF/FAS	Left	VISIT 6	09MAR2016	0.4	0.1	0.8
	ND plus	ES/SAF/FAS	Left	VISIT 7	07SEP2016	1.3	0.3	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 8	23AUG2017	1.2	0.5	0.9
01/0144	ND basic	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	23JUN2015	1.4	5.2	0
	ND basic	ES/SAF/FAS	Left	VISIT 3A	21SEP2015	0.2	0.2	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 4	03NOV2015	0.2	0.2	0.2
	ND basic	ES/SAF/FAS	Left	VISIT 5	17DEC2015	0.2	0.3	0.3
	ND basic	ES/SAF/FAS	Left	VISIT 6	30MAR2016	0.3	0.3	0.3
	ND basic	ES/SAF/FAS	Left	VISIT 7	21SEP2016	0.3	0.3	0.4
	ND basic	ES/SAF/FAS	Left	VISIT 8	30AUG2017	0.4	0.4	0.5
01/0145	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	15JUL2015	5.6	0.1	3.5
	ND plus	ES/SAF/FAS	Right	VISIT 3A	05OCT2015	1.6	0	2.7
	ND plus	ES/SAF/FAS	Right	VISIT 4	19NOV2015	1.1	0	1.4
	ND plus	ES/SAF/FAS	Right	VISIT 5	05JAN2016	0.3	0.1	0.9
	ND plus	ES/SAF/FAS	Right	VISIT 6	05APR2016	0.8	0.1	0.6
	ND plus	ES/SAF/FAS	Right	VISIT 7	05OCT2016	0.4	0.3	0.6
	ND plus	ES/SAF/FAS	Right	VISIT 8	20SEP2017	1.1	0.1	1.8
01/0146	ND plus	ES/SAF/FAS	Right	VISIT 11	30SEP2020	0.3	0.3	0.2
	SC	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	15JUL2015	3.4	7.9	0.2
	SC	ES/SAF/FAS	Left	VISIT 5	13OCT2015	4.8	0.4	0.4
	SC	ES/SAF/FAS	Left	VISIT 6	19JAN2016	4.5	0.4	2.7
	SC	ES/SAF/FAS	Left	VISIT 7	06JUL2016	6.1	0.3	0.4
	SC	ES/SAF/FAS	Left	VISIT 8	21JUN2017	1.8	3.5	0.3
	SC	ES/SAF/FAS	Left	VISIT 11	26AUG2020	4.5	3.3	6.3
01/0147	ND plus	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	19AUG2015	2.2	5.5	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 4	05JAN2016	0	0	0
	ND plus	ES/SAF/FAS	Left	VISIT 5	09FEB2016	0	0	0
	ND plus	ES/SAF/FAS	Left	VISIT 7	16NOV2016	0.1	0.2	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 8	15NOV2017	0.8	0.8	0.8
	ND plus	ES/SAF/FAS	Left	VISIT 11	04NOV2020	1.4	1.1	1.4
01/0148	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	21OCT2015	7.6	0.3	7.8

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
01/0148	ND plus	ES/SAF/FAS	Right	VISIT 3A	11JAN2016	1.1	0.4	0.5
	ND plus	ES/SAF/FAS	Right	VISIT 4	24FEB2016	1.3	0.3	0.2
	ND plus	ES/SAF/FAS	Right	VISIT 5	13APR2016	1.6	0.7	0.7
	ND plus	ES/SAF/FAS	Right	VISIT 6	20JUN2016	1.4	0.2	0.3
	ND plus	ES/SAF/FAS	Right	VISIT 7	14DEC2016	3.4	-	-
	ND plus	ES/SAF/FAS	Right	VISIT 8	13DEC2017	2.5	0.1	0.1
	ND plus	ES/SAF/FAS	Right	VISIT 11	08FEB2021	4.7	0.3	0.3
01/0149	ND plus	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	02DEC2015	0	7.8	0
	ND plus	ES/SAF/FAS	Left	VISIT 3A	01MAR2016	0.1	0	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 4	13APR2016	0.1	0.1	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 5	01JUN2016	0.1	0.1	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 6	14SEP2016	0.1	0.1	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 7	15MAR2017	0	0.2	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 8	14MAR2018	0.1	0	0.1
01/0151	ND plus	ES/SAF/FAS	Left	VISIT 11	24FEB2021	1	3.8	-
	ND basic	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	01MAR2016	6.7	0	6.7
	ND basic	ES/SAF/FAS	Right	VISIT 3A	06JUN2016	0	0	0
	ND basic	ES/SAF/FAS	Right	VISIT 4	13JUL2016	0	0	0
	ND basic	ES/SAF/FAS	Right	VISIT 5	07SEP2016	0	0	0
	ND basic	ES/SAF/FAS	Right	VISIT 6	30NOV2016	0.1	0.1	0.1
	ND basic	ES/SAF/FAS	Right	VISIT 7	31MAY2017	0.1	0	0.1
01/0152	ND basic	ES/SAF/FAS	Right	VISIT 8	02MAY2018	0	0	0
	SC	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	02MAR2016	6.2	5.9	-
	SC	ES/SAF/FAS	Left	VISIT 4	21APR2016	0	0	0
	SC	ES/SAF/FAS	Left	VISIT 5	25MAY2016	1.6	1.5	0
	SC	ES/SAF/FAS	Left	VISIT 6	24AUG2016	0.9	1	0
	SC	ES/SAF/FAS	Left	VISIT 7	22FEB2017	2.1	1.7	0.1
	SC	ES/SAF/FAS	Left	VISIT 8	07MAR2018	5	4.5	0
01/0153	SC	ES/SAF/FAS	Left	VISIT 11	10MAR2021	-	2.7	-
	ND basic	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	20MAR2016	3	0	6.8
	ND basic	ES/SAF/FAS	Right	VISIT 3A	06JUN2016	0	0	0
	ND basic	ES/SAF/FAS	Right	VISIT 4	20JUL2016	0.1	0	2.6
	ND basic	ES/SAF/FAS	Right	VISIT 5	07SEP2016	0.1	0.1	0
	ND basic	ES/SAF/FAS	Right	VISIT 6	30NOV2016	0	0	2.6
	ND basic	ES/SAF/FAS	Right	VISIT 7	31MAY2017	0	0	1.2
	ND basic	ES/SAF/FAS	Right	VISIT 8	02MAY2018	0	0	0.1
	ND basic	ES/SAF/FAS	Right	VISIT 11	14JUN2021	6.4	0	0.1

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
02/0201	ND plus	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	12FEB2013	0.3	7.9	0
	ND plus	ES/SAF/FAS	Left	VISIT 3A	07MAY2013	0	0	0
	ND plus	ES/SAF/FAS	Left	VISIT 4	20JUN2013	0.6	0.1	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 5	31JUL2013	0.1	0.1	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 6	29OCT2013	0	0	0
	ND plus	ES/SAF/FAS	Left	VISIT 7	06MAY2014	0	0	0
	ND plus	ES/SAF/FAS	Left	VISIT 8	02JUN2015	0	0	0
	ND plus	ES/SAF/FAS	Left	VISIT 11	29MAY2018	0.3	0.4	0.3
02/0202	ND basic	ES/SAF	Left	BASELINE (VISIT 2A)	19MAR2013	10	9.9	0.1
02/0203	ND basic	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	28MAR2013	8.6	10	0
	ND basic	ES/SAF/FAS	Left	VISIT 3A	25JUN2013	0.1	1.2	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 4	13AUG2013	1.7	6.7	0
	ND basic	ES/SAF/FAS	Left	VISIT 5	24SEP2013	5.1	4.1	0
	ND basic	ES/SAF/FAS	Left	VISIT 6	10DEC2013	0.5	5.6	0
	ND basic	ES/SAF/FAS	Left	UNSCHEDULED	26FEB2014	4.5	0	0.1
	ND basic	ES/SAF/FAS	Left	UNSCHEDULED	05MAR2014	8.3	0.1	8.4
	ND basic	ES/SAF/FAS	Left	VISIT 7	26JUN2014	4.2	2.2	2.4
02/0204	ND basic	ES/SAF/FAS	Left	UNSCHEDULED	20JUL2016	6.3	0.5	1.8
	ND basic	ES/SAF	Left	BASELINE (VISIT 2A)	18APR2013	3.6	2	0
	ND basic	ES/SAF/FAS	Left	VISIT 3A	30JUL2013	0.1	0.2	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 4	17SEP2013	0	0	0
	ND basic	ES/SAF/FAS	Left	VISIT 5	28OCT2013	0	0	0
	ND basic	ES/SAF/FAS	Left	VISIT 6	23JAN2014	0.2	0.1	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 7	12AUG2014	0.1	0.3	0.3
	ND basic	ES/SAF/FAS	Left	VISIT 8	21AUG2015	0.9	0.8	1
02/0205	ND basic	ES/SAF/FAS	Left	VISIT 11	28AUG2018	0	0	0
	ND plus	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	27JUN2013	0.9	5.3	0
	ND plus	ES/SAF/FAS	Left	VISIT 3A	07OCT2013	2.6	0	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 4	20NOV2013	3	0.1	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 5	03JAN2014	2.2	0.9	0.9
	ND plus	ES/SAF/FAS	Left	VISIT 6	07MAR2014	0.2	0.2	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 7	05AUG2014	0.5	0.3	0.3
	ND plus	ES/SAF/FAS	Left	VISIT 11	30AUG2018	2	0	0.4
02/0206	ES		Right	BASELINE (VISIT 2A)	23JUL2013	8.8	0	1.7

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
02/0208	ND plus	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	11SEP2013	3.7	3.5	0.3
	ND plus	ES/SAF/FAS	Left	VISIT 3A	09DEC2013	0.4	0.4	0.7
	ND plus	ES/SAF/FAS	Left	UNSCHEDULED	16DEC2013	1.6	7.7	0.8
	ND plus	ES/SAF/FAS	Left	VISIT 4	22JAN2014	1.4	1.5	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 5	25MAR2014	1.8	2.8	0
	ND plus	ES/SAF/FAS	Left	UNSCHEDULED	01APR2014	1.4	2.7	0
	ND plus	ES/SAF/FAS	Left	VISIT 6	28MAY2014	2.9	0.3	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 7	30DEC2014	0.7	0.3	0
	ND plus	ES/SAF/FAS	Left	UNSCHEDULED	01SEP2015	2.2	7.8	0.3
	ND plus	ES/SAF/FAS	Left	VISIT 8	17DEC2015	0	0.1	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 11	27DEC2018	0.2	0.2	0.2
02/0209	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	22OCT2014	3.8	0	3.9
	ND plus	ES/SAF/FAS	Right	VISIT 3A	29JAN2015	0.1	0.2	0.2
	ND plus	ES/SAF/FAS	Right	VISIT 4	24MAR2015	2.2	0.1	0.2
	ND plus	ES/SAF/FAS	Right	VISIT 5	29APR2015	0	0	0
	ND plus	ES/SAF/FAS	Right	VISIT 6	16JUL2015	0.2	0	0.2
	ND plus	ES/SAF/FAS	Right	VISIT 7	23FEB2016	0.9	0.3	0.2
	ND plus	ES/SAF/FAS	Right	VISIT 8	19JAN2017	0.3	0.2	0.1
	ND plus	ES/SAF/FAS	Right	VISIT 11	30DEC2019	0.5	0.1	0.1
02/0210		ES		BASELINE (VISIT 2A)	12NOV2014	4.7	6.3	0
02/0211	ND basic	ES/SAF	Right	BASELINE (VISIT 2A)	11DEC2014	0.1	0.2	4.1
	ND basic	ES/SAF	Right	VISIT 3A	04MAR2015	3.4	-	3.5
02/0212	SC	ES/SAF/FAS	Left	VISIT 4	30JAN2015	3.2	0	0
	SC	ES/SAF/FAS	Left	VISIT 5	10APR2015	2.5	0.1	0
	SC	ES/SAF/FAS	Left	VISIT 6	25JUN2015	2.2	0.3	0
	SC	ES/SAF/FAS	Left	VISIT 7	28JAN2016	4.4	0.2	0.1
	SC	ES/SAF/FAS	Left	VISIT 8	28DEC2016	1.9	1.7	0.1
	SC	ES/SAF/FAS	Left	VISIT 11	27DEC2019	1.9	0.6	0.1
02/0213	ND plus	ES/SAF	Left	BASELINE (VISIT 2A)	17DEC2014	1	5.4	0.1
02/0214	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	24FEB2015	5.6	0.2	5.6
	ND plus	ES/SAF/FAS	Right	VISIT 3A	27MAY2015	1.2	0.2	0.7
	ND plus	ES/SAF/FAS	Right	VISIT 4	23JUL2015	1.6	0.1	0.6
	ND plus	ES/SAF/FAS	Right	VISIT 6	03DEC2015	7.3	0.3	7.3
	ND plus	ES/SAF/FAS	Right	VISIT 7	26MAY2016	2.6	0.4	0.6
	ND plus	ES/SAF/FAS	Right	VISIT 11	15OCT2020	4	0	2.8

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
02/0215		ES	Left	BASELINE (VISIT 2A)	04MAR2015	7.8	7.9	7.9
02/0216	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	27APR2015	8.1	0	8.3
	ND plus	ES/SAF/FAS	Right	VISIT 3A	22JUL2015	1.3	-	2.2
	ND plus	ES/SAF/FAS	Right	VISIT 5	21OCT2015	5	0	0.1
02/0217	SC	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	27MAY2015	4.7	0.1	8.5
	SC	ES/SAF/FAS	Left	VISIT 4	14JUL2015	0.3	0.3	0.3
	SC	ES/SAF/FAS	Left	VISIT 5	30AUG2015	0.2	0.3	0.4
	SC	ES/SAF/FAS	Left	VISIT 6	08DEC2015	0.1	0.3	0.1
	SC	ES/SAF/FAS	Left	VISIT 7	11MAY2016	0	0	0
	SC	ES/SAF/FAS	Left	VISIT 8	27APR2017	0.2	0.2	0.2
	SC	ES/SAF/FAS	Left	VISIT 11	01JUL2020	0.2	0.2	0.2
02/0219	ND basic	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	10JUN2015	4.5	7.2	0.6
	ND basic	ES/SAF/FAS	Left	VISIT 3A	24SEP2015	2.3	1.2	0
	ND basic	ES/SAF/FAS	Left	VISIT 4	04NOV2015	1.5	0.7	0
	ND basic	ES/SAF/FAS	Left	VISIT 5	17DEC2015	3.4	2.7	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 6	04APR2016	1.4	0.5	0
	ND basic	ES/SAF/FAS	Left	VISIT 7	22AUG2016	2.4	0.1	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 8	20SEP2017	0	0	0
	ND basic	ES/SAF/FAS	Left	VISIT 11	26AUG2020	0.3	1.1	0.2
02/0220	SC	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	12AUG2015	0.2	8.6	0.2
	SC	ES/SAF/FAS	Left	VISIT 4	29SEP2015	2	0.1	0
	SC	ES/SAF/FAS	Left	VISIT 5	17NOV2015	0.3	0.4	0
	SC	ES/SAF/FAS	Left	VISIT 6	26JAN2016	0.1	0	0
	SC	ES/SAF/FAS	Left	VISIT 7	04AUG2016	0.3	0	0
	SC	ES/SAF/FAS	Left	VISIT 8	19JUL2017	0.9	0.1	0.1
	SC	ES/SAF/FAS	Left	VISIT 11	02SEP2020	4.5	7.2	0.2
02/0221	ND plus	ES/SAF	Left	BASELINE (VISIT 2A)	31AUG2015	6.7	6.8	0
02/0222	ND plus	ES/SAF	Right	BASELINE (VISIT 2A)	09SEP2015	2.6	0.1	7.7
02/0223	ND basic	ES/SAF/FAS	Right	VISIT 3A	21MAR2016	1.2	0	1.1
	ND basic	ES/SAF/FAS	Right	VISIT 4	27APR2016	-	-	1.6
	ND basic	ES/SAF/FAS	Right	VISIT 5	05JUL2016	0	0	0.5
	ND basic	ES/SAF/FAS	Right	VISIT 6	24AUG2016	0.8	0	0.5
	ND basic	ES/SAF/FAS	Right	VISIT 7	15MAR2017	0.8	-	0.8
	ND basic	ES/SAF/FAS	Right	VISIT 8	07MAR2018	0.7	-	-

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
02/0223	ND basic	ES/SAF/FAS	Right	VISIT 11	03MAR2021	1.3	-	-
02/0224	ND plus	ES/SAF	Right	BASELINE (VISIT 2A)	28DEC2015	7.8	0.3	7.5
04/0401	SC	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	28JUN2015	1.5	0.1	7.5
	SC	ES/SAF/FAS	Right	VISIT 4	11AUG2015	1.3	0.1	1.8
	SC	ES/SAF/FAS	Right	VISIT 5	08OCT2015	0.8	0.1	0.9
	SC	ES/SAF/FAS	Right	VISIT 6	16DEC2015	1	0.3	0.7
	SC	ES/SAF/FAS	Right	VISIT 7	21JUN2016	0.1	0.1	0.1
	SC	ES/SAF/FAS	Right	VISIT 8	05JUL2017	0	0	0
	SC	ES/SAF/FAS	Right	VISIT 11	27JUL2020	0	0	0
06/0602	ND plus	ES/SAF/FAS	Left	VISIT 3A	04NOV2013	1.7	0.2	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 4	18DEC2013	3.1	0.3	0
	ND plus	ES/SAF/FAS	Left	VISIT 5	12FEB2014	0	2.2	0
	ND plus	ES/SAF/FAS	Left	VISIT 6	22APR2014	4.4	0.1	0.1
06/0604	ND basic	ES/SAF	Right	BASELINE (VISIT 2A)	27OCT2014	6	0.3	9.3
06/0606	SC	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	15DEC2014	5.7	0.2	7.6
	SC	ES/SAF/FAS	Right	VISIT 4	10FEB2015	0.9	3.5	6.1
	SC	ES/SAF/FAS	Right	VISIT 5	12MAR2015	7.1	5.6	8.9
	SC	ES/SAF/FAS	Right	VISIT 6	03JUN2015	3.6	2.1	4.2
	SC	ES/SAF/FAS	Right	VISIT 7	03DEC2015	5.8	4	7
	SC	ES/SAF/FAS	Right	VISIT 8	24NOV2016	5.5	1.3	5.4
	SC	ES/SAF/FAS	Right	VISIT 11	03DEC2019	1.1	0.9	0.9
06/0607	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	19JAN2015	0.1	0	8.1
	ND plus	ES/SAF/FAS	Right	VISIT 4	01JUN2015	1.3	1.1	2.1
	ND plus	ES/SAF/FAS	Right	VISIT 5	21JUL2015	-	-	2.3
	ND plus	ES/SAF/FAS	Right	VISIT 8	05APR2017	4.6	5.4	5.4
	ND plus	ES/SAF/FAS	Right	VISIT 11	16MAR2020	2.2	0	1.4
06/0609	ND basic	ES/SAF	Right	BASELINE (VISIT 2A)	15APR2015	2.1	0.2	3.1
06/0610	ND plus	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	24JUN2015	7.4	7.5	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 3A	07SEP2015	1.1	0.5	0
	ND plus	ES/SAF/FAS	Left	VISIT 4	26OCT2015	0.2	1.1	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 5	14DEC2015	2	3.6	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 6	16MAR2016	0.1	0.9	0
	ND plus	ES/SAF/FAS	Left	VISIT 7	30AUG2016	1.1	0.4	0.2

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
06/0610	ND plus	ES/SAF/FAS	Left	VISIT 8	10OCT2017	0.5	0.3	0.3
	ND plus	ES/SAF/FAS	Left	VISIT 11	07SEP2020	0.2	0.3	0.2
06/0611		ES	Left	BASELINE (VISIT 2A)	14JUL2015	1	7.9	0.3
06/0612	ND plus	ES/SAF/FAS	Left	VISIT 3A	19OCT2015	0.9	1.8	0.3
	ND plus	ES/SAF/FAS	Left	VISIT 4	25NOV2015	1.5	3.1	0.3
	ND plus	ES/SAF/FAS	Left	VISIT 5	11JAN2016	1.2	2.5	0.3
	ND plus	ES/SAF/FAS	Left	VISIT 6	11APR2016	0.4	1.5	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 7	26OCT2016	0.8	1.5	0.3
	ND plus	ES/SAF/FAS	Left	VISIT 8	19OCT2017	0.6	1.4	0.6
	ND plus	ES/SAF/FAS	Left	VISIT 11	14OCT2020	0.5	1.7	0.3
06/0613	SC	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	17JUL2015	8	-	6.9
	SC	ES/SAF/FAS	Right	VISIT 4	04SEP2015	0.8	-	0.9
	SC	ES/SAF/FAS	Right	VISIT 5	15OCT2015	1.5	0.5	0.5
	SC	ES/SAF/FAS	Right	VISIT 6	15JAN2016	1.2	0.2	0.3
	SC	ES/SAF/FAS	Right	VISIT 8	09AUG2017	5.9	0.2	0.2
	SC	ES/SAF/FAS	Right	VISIT 11	11AUG2020	1.1	0.2	0.2
06/0614	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	14AUG2015	8.5	0.1	8.9
	ND plus	ES/SAF/FAS	Right	VISIT 3A	18NOV2015	2.5	0.2	1.4
	ND plus	ES/SAF/FAS	Right	VISIT 4	04JAN2016	1.5	0	0
	ND plus	ES/SAF/FAS	Right	VISIT 5	09FEB2016	7.9	0	4.3
	ND plus	ES/SAF/FAS	Right	VISIT 6	02MAY2016	2.5	0.1	0.7
	ND plus	ES/SAF/FAS	Right	VISIT 7	17NOV2016	3	0.1	3.3
	ND plus	ES/SAF/FAS	Right	VISIT 8	02NOV2017	4.8	0	0
	ND plus	ES/SAF/FAS	Right	VISIT 11	10DEC2020	0.1	0.1	0
06/0615	ND basic	ES/SAF	Right	BASELINE (VISIT 2A)	21AUG2015	1.8	0	4
06/0616		ES	Right	BASELINE (VISIT 2A)	05NOV2015	5.3	0	2.8
06/0617	ND plus	ES/SAF	Right	BASELINE (VISIT 2A)	21DEC2015	4.4	0.1	5.1
	ND plus	ES/SAF	Right	VISIT 3A	08MAR2016	3	0	5.9
06/0618		ES	Right	BASELINE (VISIT 2A)	14JAN2016	1.2	0.1	1.9
06/0619	ND basic	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	22FEB2016	5.3	0.2	5.7
	ND basic	ES/SAF/FAS	Right	VISIT 3A	09MAY2016	0.1	0.1	0.2
	ND basic	ES/SAF/FAS	Right	VISIT 4	20JUN2016	5.1	0	3.6

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
06/0619	ND basic	ES/SAF/FAS	Right	VISIT 5	04AUG2016	0.6	0.1	0.4
	ND basic	ES/SAF/FAS	Right	VISIT 6	03NOV2016	1.8	0.1	1.6
	ND basic	ES/SAF/FAS	Right	VISIT 7	15MAY2017	1.2	0.1	0.9
	ND basic	ES/SAF/FAS	Right	VISIT 8	02MAY2018	3.1	0.1	0.4
	ND basic	ES/SAF/FAS	Right	VISIT 11	28MAY2021	1.3	1.3	1.2
06/0620	SC	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	23FEB2016	5.5	3.6	0.1
	SC	ES/SAF/FAS	Left	VISIT 4	12APR2016	2.6	0.7	0.1
	SC	ES/SAF/FAS	Left	VISIT 5	23MAY2016	3.1	0	0
	SC	ES/SAF/FAS	Left	VISIT 6	17AUG2016	3.1	0.8	0
	SC	ES/SAF/FAS	Left	VISIT 7	20FEB2017	3.4	0	0
	SC	ES/SAF/FAS	Left	VISIT 8	26MAR2018	1.9	0.9	0
	SC	ES/SAF/FAS	Left	VISIT 11	02MAR2021	2.2	0	0
07/0701	ND plus	ES/SAF/FAS	Right	VISIT 3A	19JAN2014	0.3	0	0.1
	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	05NOV2014	0.6	0.1	2.6
	ND plus	ES/SAF/FAS	Right	VISIT 4	04MAR2015	0.4	0.1	0.4
	ND plus	ES/SAF/FAS	Right	VISIT 5	27APR2015	0.4	0.1	0.4
	ND plus	ES/SAF/FAS	Right	VISIT 6	20JUL2015	0.6	0	0.5
	ND plus	ES/SAF/FAS	Right	VISIT 7	14JAN2016	0.8	0	0.8
	ND plus	ES/SAF/FAS	Right	VISIT 8	30JAN2017	1.1	0.1	1.2
	ND plus	ES/SAF/FAS	Right	VISIT 11	12FEB2020	1.7	0.3	1.1
07/0702	SC	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	19JAN2015	5.5	0.2	8.3
	SC	ES/SAF/FAS	Right	VISIT 4	02MAR2015	2.1	0.1	0.5
	SC	ES/SAF/FAS	Right	VISIT 5	20APR2015	2.3	0	0
	SC	ES/SAF/FAS	Right	VISIT 6	21JUL2015	0.8	0	0
	SC	ES/SAF/FAS	Right	VISIT 8	14FEB2018	2.4	0.9	0.8
07/0703	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	02MAR2015	0.2	0.2	2.8
	ND plus	ES/SAF/FAS	Right	VISIT 3A	18MAY2015	0.2	-	-
	ND plus	ES/SAF/FAS	Right	VISIT 4	29JUN2015	0.2	0.2	0.2
	ND plus	ES/SAF/FAS	Right	VISIT 5	17AUG2015	0.2	0.1	0.2
	ND plus	ES/SAF/FAS	Right	VISIT 6	09NOV2015	0.2	0.1	0.2
	ND plus	ES/SAF/FAS	Right	VISIT 7	09MAY2016	1	0.1	0.2
	ND plus	ES/SAF/FAS	Right	VISIT 11	20JUL2020	0.1	0.2	0.2
07/0704	ND basic	ES/SAF/FAS	Left	VISIT 3A	06OCT2015	0.5	0.1	0
	ND basic	ES/SAF/FAS	Left	VISIT 4	16NOV2015	1.4	0.3	0.3
	ND basic	ES/SAF/FAS	Left	VISIT 5	11JAN2016	2.7	0	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 6	11APR2016	1	0.9	0.2

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
07/0704	ND basic	ES/SAF/FAS	Left	VISIT 7	21NOV2016	0.7	0	0
	ND basic	ES/SAF/FAS	Left	VISIT 8	02OCT2017	0.2	0.2	0.3
	ND basic	ES/SAF/FAS	Left	VISIT 11	21SEP2020	0.1	0.1	0.1
07/0705		ES	Right	BASELINE (VISIT 2A)	12AUG2015	-	-	9.7
07/0706	SC	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	30NOV2015	0.1	0.1	5
	SC	ES/SAF/FAS	Right	VISIT 4	12JAN2016	6.3	0	0
07/0707		ES	Left	BASELINE (VISIT 2A)	17FEB2016	5.9	9.1	0.5
08/0801	SC	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	31OCT2014	1.5	8	0.2
	SC	ES/SAF/FAS	Left	VISIT 4	22DEC2014	5.2	5.3	0.3
	SC	ES/SAF/FAS	Left	VISIT 5	12FEB2015	2.7	3.9	0.3
	SC	ES/SAF/FAS	Left	VISIT 6	04MAY2015	2.6	4.6	0.6
08/0802	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	26NOV2014	3.4	0	4.3
	ND plus	ES/SAF/FAS	Right	VISIT 3A	03MAR2015	0.8	0.4	1.1
	ND plus	ES/SAF/FAS	Right	VISIT 4	08APR2015	0.8	0.1	0.3
	ND plus	ES/SAF/FAS	Right	VISIT 5	01JUN2015	0.7	0	0
	ND plus	ES/SAF/FAS	Right	VISIT 6	17AUG2015	1.5	0	0.2
	ND plus	ES/SAF/FAS	Right	VISIT 7	22FEB2016	1.8	0	0.7
	ND plus	ES/SAF/FAS	Right	VISIT 11	19MAR2020	1.9	0	1.6
08/0803	ND basic	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	24FEB2015	0.4	0.6	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 3A	15JUN2015	0.3	0.1	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 4	24JUL2015	0.1	0	0
	ND basic	ES/SAF/FAS	Left	VISIT 5	07SEP2015	0.3	0.2	0.3
08/0804	ND plus	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	22MAY2015	2.1	9.1	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 3A	20AUG2015	0.2	0.3	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 4	28SEP2015	1.3	0.3	0.3
	ND plus	ES/SAF/FAS	Left	VISIT 5	13NOV2015	0.3	0.2	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 6	05FEB2016	0.6	0.2	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 7	22AUG2016	0.6	0.1	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 8	04AUG2017	2.9	0.3	0.3
	ND plus	ES/SAF/FAS	Left	VISIT 11	04AUG2020	0.4	0.4	0.3
08/0805	ND basic	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	24JUN2015	6.6	6.6	6.7
	ND basic	ES/SAF/FAS	Right	VISIT 3A	21SEP2015	1.4	0.1	3
	ND basic	ES/SAF/FAS	Right	VISIT 4	02NOV2015	4	1.2	4.4

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
08/0805	ND basic	ES/SAF/FAS	Right	VISIT 5	21DEC2015	3	0.3	1.1
	ND basic	ES/SAF/FAS	Right	VISIT 6	07MAR2016	1	0.2	0
	ND basic	ES/SAF/FAS	Right	VISIT 7	14FEB2017	2.7	0.1	0.9
	ND basic	ES/SAF/FAS	Right	VISIT 8	28AUG2017	1.7	0	0.4
	ND basic	ES/SAF/FAS	Right	VISIT 11	03SEP2020	6.4	0	0
08/0806	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	07JUL2015	0.3	0.3	0.3
	ND plus	ES/SAF/FAS	Right	VISIT 3A	28SEP2015	2.6	0.6	0.4
	ND plus	ES/SAF/FAS	Right	VISIT 4	06NOV2015	-	0	0
	ND plus	ES/SAF/FAS	Right	VISIT 5	23DEC2015	0.3	0.3	3.2
	ND plus	ES/SAF/FAS	Right	VISIT 6	14MAR2016	2.3	0.1	0.1
	ND plus	ES/SAF/FAS	Right	VISIT 7	27SEP2016	1.7	0.3	0.5
	ND plus	ES/SAF/FAS	Right	VISIT 8	12OCT2017	1.9	0.6	0.8
08/0807	ND plus	ES/SAF/FAS	Right	VISIT 11	24SEP2020	1.5	-	-
	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	18NOV2015	7.9	2.6	4.9
	ND plus	ES/SAF/FAS	Right	VISIT 3A	01FEB2016	8.6	0	0
	ND plus	ES/SAF/FAS	Right	VISIT 4	16MAR2016	2.2	0.3	4.6
	ND plus	ES/SAF/FAS	Right	VISIT 5	03MAY2016	1.3	0.3	1
	ND plus	ES/SAF/FAS	Right	VISIT 6	28JUL2016	1.4	0	0
	ND plus	ES/SAF/FAS	Right	VISIT 7	06FEB2017	0.6	0.3	0.2
08/0808	ND plus	ES/SAF/FAS	Right	VISIT 8	19FEB2018	3.5	0.9	2.6
	SC	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	02DEC2015	1.9	0.3	6.2
	SC	ES/SAF/FAS	Right	VISIT 4	07JAN2016	1.1	0	1.6
	SC	ES/SAF/FAS	Right	VISIT 5	26FEB2016	0.7	0.2	0.8
	SC	ES/SAF/FAS	Right	VISIT 6	03JUN2016	0.1	0.1	0.5
	SC	ES/SAF/FAS	Right	VISIT 7	28NOV2016	0.8	0	0
	SC	ES/SAF/FAS	Right	VISIT 8	13NOV2017	0.1	0	0
09/0901	SC	ES/SAF/FAS	Right	VISIT 11	28DEC2020	0.4	0	0.3
	SC	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	29OCT2014	0.3	0.2	6.9
	SC	ES/SAF/FAS	Right	VISIT 4	08DEC2014	0.4	0	2.8
	SC	ES/SAF/FAS	Right	VISIT 5	27JAN2015	1.3	0.1	1.2
	SC	ES/SAF/FAS	Right	VISIT 6	05MAY2015	0	0	1.2
	SC	ES/SAF/FAS	Right	VISIT 7	03NOV2015	0.1	0	1.5
	SC	ES/SAF/FAS	Right	VISIT 8	22NOV2016	0.1	0.1	0.4
09/0903	SC	ES/SAF/FAS	Right	VISIT 11	28OCT2019	0.1	0.1	0
	ND plus	ES/SAF	Right	BASELINE (VISIT 2A)	19NOV2014	2.4	0	2.2
	ND plus	ES/SAF	Right	VISIT 3A	11FEB2015	2.2	0	0.8

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
09/0904	ND basic	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	05FEB2015	4.1	9.4	-
	ND basic	ES/SAF/FAS	Left	VISIT 3A	20MAY2015	0.5	2.5	0.3
	ND basic	ES/SAF/FAS	Left	VISIT 4	08JUL2015	0	6.9	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 5	26AUG2015	0.4	0.1	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 6	17NOV2015	0.9	0.8	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 7	23MAY2016	1.1	3.1	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 8	24APR2017	1.5	3.3	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 11	11MAY2020	2.6	2.9	0.1
09/0905	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	18MAR2015	7.1	-	7.8
	ND plus	ES/SAF/FAS	Right	VISIT 3A	24JUN2015	3.1	0.2	1.9
	ND plus	ES/SAF/FAS	Right	VISIT 4	10AUG2015	4.5	0.2	1.7
	ND plus	ES/SAF/FAS	Right	VISIT 5	28SEP2015	1.4	0.1	0.6
	ND plus	ES/SAF/FAS	Right	VISIT 6	21DEC2015	0.5	0.7	0.9
	ND plus	ES/SAF/FAS	Right	VISIT 7	20JUN2016	0.4	0.8	1.2
	ND plus	ES/SAF/FAS	Right	VISIT 8	19JUN2017	1.4	0.6	3.6
	ND plus	ES/SAF/FAS	Right	VISIT 11	25MAY2020	1.8	0.1	1.3
09/0906		ES	Right	BASELINE (VISIT 2A)	26MAR2015	0.8	0.1	5.4
09/0907	SC	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	13APR2015	2.8	2.1	0.1
	SC	ES/SAF/FAS	Left	VISIT 4	26MAY2015	0	0	0
	SC	ES/SAF/FAS	Left	VISIT 5	14JUL2015	0	0	0
	SC	ES/SAF/FAS	Left	VISIT 6	09NOV2015	0.7	0.8	0
	SC	ES/SAF/FAS	Left	VISIT 7	04APR2016	1.4	0	0
	SC	ES/SAF/FAS	Left	VISIT 8	10APR2017	0	0.1	0.1
	SC	ES/SAF/FAS	Left	VISIT 11	12MAY2020	0	0	0
09/0908	ND basic	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	05MAY2015	1.1	1.1	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 3A	05AUG2015	0.1	0.1	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 4	21SEP2015	0	0	0
	ND basic	ES/SAF/FAS	Left	VISIT 5	02NOV2015	0.1	0.1	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 6	25JAN2016	0	0	0
	ND basic	ES/SAF/FAS	Left	VISIT 7	20JUL2016	0	0.1	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 8	17JUL2017	0.8	0.1	0
	ND basic	ES/SAF/FAS	Left	VISIT 11	22JUN2020	0.2	0.2	0.2
09/0909	ND plus	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	11MAY2015	2.6	5	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 3A	12AUG2015	0.4	0.3	0.3
	ND plus	ES/SAF/FAS	Left	VISIT 4	28SEP2015	0.6	0.2	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 5	09NOV2015	0.7	0.3	0.3

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
09/0909	ND plus	ES/SAF/FAS	Left	VISIT 6	01FEB2016	0.4	0.2	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 7	18JUL2016	0.1	0.1	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 8	24JUL2017	0.6	0.2	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 11	27JUL2020	0.2	0.2	0.2
09/0910	ND plus	ES/SAF	Left	BASELINE (VISIT 2A)	31AUG2015	8.1	8.1	0.2
09/0911	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	15OCT2015	8.3	1.7	6.7
	ND plus	ES/SAF/FAS	Right	VISIT 3A	13JAN2016	4.8	1.4	3.6
	ND plus	ES/SAF/FAS	Right	VISIT 4	22FEB2016	3	0.2	1
	ND plus	ES/SAF/FAS	Right	VISIT 5	11APR2016	1.4	0	0.3
	ND plus	ES/SAF/FAS	Right	VISIT 6	04JUL2016	1.5	0	0.1
	ND plus	ES/SAF/FAS	Right	VISIT 7	16JAN2017	2.2	0.1	0.4
	ND plus	ES/SAF/FAS	Right	VISIT 8	29JAN2018	1.4	0	0.6
	ND plus	ES/SAF/FAS	Right	VISIT 11	18JAN2021	0.4	0	0.1
09/0912	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	19OCT2015	1.6	0.4	8.6
	ND plus	ES/SAF/FAS	Right	VISIT 3A	20JAN2016	0.8	0	0.6
	ND plus	ES/SAF/FAS	Right	VISIT 4	29FEB2016	0.6	0.5	0.4
	ND plus	ES/SAF/FAS	Right	VISIT 5	25APR2016	0	0	0
	ND plus	ES/SAF/FAS	Right	VISIT 6	25JUL2016	0	0	0
	ND plus	ES/SAF/FAS	Right	VISIT 7	23JAN2017	0.2	0.2	0.2
	ND plus	ES/SAF/FAS	Right	VISIT 8	15JAN2018	0	0	0
	ND plus	ES/SAF/FAS	Right	VISIT 11	25JAN2021	0.5	0.1	0
09/0913	ND basic	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	26NOV2015	3.2	0.2	3.7
	ND basic	ES/SAF/FAS	Right	VISIT 3A	17FEB2016	1.2	0	1.7
	ND basic	ES/SAF/FAS	Right	VISIT 4	04APR2016	0.6	0.1	0.5
	ND basic	ES/SAF/FAS	Right	VISIT 5	23MAY2016	1.9	0.2	0.9
	ND basic	ES/SAF/FAS	Right	VISIT 6	08AUG2016	0.3	0.2	0.2
	ND basic	ES/SAF/FAS	Right	VISIT 7	30JAN2017	2.6	0.2	0.2
	ND basic	ES/SAF/FAS	Right	VISIT 8	05FEB2018	1.7	0.1	0.1
	ND basic	ES/SAF/FAS	Right	VISIT 11	08MAR2021	0.4	0.3	0.3
09/0914	SC	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	04JAN2016	7.5	7.6	0.8
	SC	ES/SAF/FAS	Left	VISIT 4	15FEB2016	1.8	2	0
	SC	ES/SAF/FAS	Left	VISIT 5	11APR2016	1.4	0	0
	SC	ES/SAF/FAS	Left	VISIT 6	27JUN2016	2.2	2	0.1
	SC	ES/SAF/FAS	Left	VISIT 7	09JAN2017	0.5	0.1	0.2
	SC	ES/SAF/FAS	Left	VISIT 8	08JAN2018	3	1.4	1.3
	SC	ES/SAF/FAS	Left	VISIT 11	11JAN2021	0.3	0.9	1

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
09/0915	ND basic	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	05JAN2016	7.6	0	2.2
	ND basic	ES/SAF/FAS	Right	VISIT 3A	23MAR2016	0.5	0.1	0.1
	ND basic	ES/SAF/FAS	Right	VISIT 4	02MAY2016	0.1	0.1	0
	ND basic	ES/SAF/FAS	Right	VISIT 5	20JUN2016	0.1	0.1	0.1
	ND basic	ES/SAF/FAS	Right	VISIT 6	26SEP2016	0.1	0.1	0.1
	ND basic	ES/SAF/FAS	Right	VISIT 7	03APR2017	0	0	0
	ND basic	ES/SAF/FAS	Right	VISIT 8	09APR2018	0.1	0.1	0.2
	ND basic	ES/SAF/FAS	Right	VISIT 11	22FEB2021	0.9	0	0
09/0916	SC	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	22FEB2016	1.9	0.3	9
	SC	ES/SAF/FAS	Right	VISIT 4	06APR2016	5.2	0	0.1
	SC	ES/SAF/FAS	Right	VISIT 5	30MAY2016	4.3	0	0.1
	SC	ES/SAF/FAS	Right	VISIT 6	29AUG2016	2	0	0.1
	SC	ES/SAF/FAS	Right	VISIT 7	20FEB2017	3	0	0
	SC	ES/SAF/FAS	Right	VISIT 8	26FEB2018	2.3	0	0
	SC	ES/SAF/FAS	Right	VISIT 11	01MAR2021	0.2	0.3	0.2
10/1001		ES	Right	BASELINE (VISIT 2A)	30NOV2015	4	0.1	5.7
11/1101	ND plus	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	12JAN2015	0.8	3.6	0.3
	ND plus	ES/SAF/FAS	Left	VISIT 3A	30MAR2015	1.3	0.2	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 4	11MAY2015	0.7	0.1	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 5	03JUL2015	0.6	0.2	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 6	09OCT2015	4.6	0.2	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 7	08APR2016	1.3	0.9	-
	ND plus	ES/SAF/FAS	Left	VISIT 8	24JAN2017	6.1	3.8	1.3
	ND plus	ES/SAF/FAS	Left	VISIT 11	14APR2020	8.1	5.6	5.5
11/1102	ND basic	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	15APR2015	7.1	9.2	0.6
	ND basic	ES/SAF/FAS	Left	VISIT 3A	27JUL2015	0.2	0.2	0.2
	ND basic	ES/SAF/FAS	Left	VISIT 4	11SEP2015	0.5	0.2	0.1
	ND basic	ES/SAF/FAS	Left	VISIT 5	23OCT2015	0.7	0.1	0.2
	ND basic	ES/SAF/FAS	Left	VISIT 6	05FEB2016	1.2	0.1	0.2
	ND basic	ES/SAF/FAS	Left	VISIT 7	29JUL2016	0.8	0.2	0.2
	ND basic	ES/SAF/FAS	Left	VISIT 8	14JUL2017	0.9	0.4	0.2
	ND basic	ES/SAF/FAS	Left	VISIT 11	18AUG2020	1.1	0.2	0.2
11/1103	SC	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	03AUG2015	8.3	5.5	0.1
	SC	ES/SAF/FAS	Left	VISIT 4	18SEP2015	2.7	2.8	0
	SC	ES/SAF/FAS	Left	VISIT 5	06NOV2015	0.5	0.5	0.1
	SC	ES/SAF/FAS	Left	VISIT 6	12FEB2016	0.3	0.3	0.3

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
11/1103	SC	ES/SAF/FAS	Left	VISIT 7	05AUG2016	2.4	0.3	0.1
	SC	ES/SAF/FAS	Left	VISIT 8	04AUG2017	2.9	1.6	0
	SC	ES/SAF/FAS	Left	VISIT 11	25AUG2020	4.9	0.2	0.2
11/1104	ND plus	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	07MAR2016	1	4.8	0
	ND plus	ES/SAF/FAS	Left	VISIT 3A	06JUN2016	0	0	0
	ND plus	ES/SAF/FAS	Left	VISIT 4	22JUL2016	0	0	0
	ND plus	ES/SAF/FAS	Left	VISIT 5	09SEP2016	0.2	0.2	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 6	25NOV2016	0.2	0.1	0.2
	ND plus	ES/SAF/FAS	Left	VISIT 7	30MAY2017	0.3	0.2	0.3
	ND plus	ES/SAF/FAS	Left	VISIT 8	12JUN2018	0.1	0.1	0.1
	ND plus	ES/SAF/FAS	Left	VISIT 11	28MAY2021	0.4	0.1	0.3
12/1201	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	07SEP2015	1.3	-	8.1
	ND plus	ES/SAF/FAS	Right	VISIT 3A	30NOV2015	0.1	0	0
	ND plus	ES/SAF/FAS	Right	VISIT 4	08JAN2016	7.5	0.1	0
	ND plus	ES/SAF/FAS	Right	VISIT 5	26FEB2016	2.4	3.6	0.1
	ND plus	ES/SAF/FAS	Right	VISIT 6	18MAY2016	7.6	7.8	0
	ND plus	ES/SAF/FAS	Right	VISIT 7	22NOV2016	3.8	1.2	0.3
	ND plus	ES/SAF/FAS	Right	VISIT 8	21NOV2017	2.4	0.3	0.2
	ND plus	ES/SAF/FAS	Right	VISIT 11	01DEC2020	0.3	0	0.2
13/1301	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	26APR2015	2.9	0.1	2.3
	ND plus	ES/SAF/FAS	Right	VISIT 3A	28JUL2015	0.8	0.1	2.9
	ND plus	ES/SAF/FAS	Right	VISIT 4	08SEP2015	2.2	0.1	2.1
	ND plus	ES/SAF/FAS	Right	VISIT 5	22OCT2015	1.3	0.1	1.4
	ND plus	ES/SAF/FAS	Right	VISIT 6	11JAN2016	1.9	0	0.9
	ND plus	ES/SAF/FAS	Right	VISIT 7	20JUL2016	1.5	0.7	1.5
	ND plus	ES/SAF/FAS	Right	VISIT 8	28JUN2017	1.8	0	0.7
	ND plus	ES/SAF/FAS	Right	VISIT 11	24JUN2020	2.3	0	2.2
13/1302	ND plus	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	11MAY2015	3.3	2.1	3.6
	ND plus	ES/SAF/FAS	Right	VISIT 3A	28JUL2015	1.5	0.3	0.3
	ND plus	ES/SAF/FAS	Right	VISIT 4	08SEP2015	1.4	0.3	1.5
	ND plus	ES/SAF/FAS	Right	VISIT 5	22OCT2015	0.4	0.4	0.7
	ND plus	ES/SAF/FAS	Right	VISIT 6	11JAN2016	0.5	0.2	0.5
	ND plus	ES/SAF/FAS	Right	VISIT 7	19JUL2016	0.2	0.2	0.2
	ND plus	ES/SAF/FAS	Right	VISIT 8	19JUL2017	1	0.3	0.4
	ND plus	ES/SAF/FAS	Right	VISIT 11	01JUL2020	3.4	1.5	1.6
13/1303	SC	ES/SAF/FAS	Right	BASELINE (VISIT 2A)	25JUN2015	2	0.1	7.2

Listing 16.2.2.2: Visual Analog Scale for Pain - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Affected Leg	Visit	Date of evaluation	Pain in the back	Pain left leg	Pain right leg
13/1303	SC	ES/SAF/FAS	Right	VISIT 5	29SEP2015	0.2	0.3	0.2
	SC	ES/SAF/FAS	Right	VISIT 6	14DEC2015	0.2	0.3	0.3
	SC	ES/SAF/FAS	Right	VISIT 7	06JUL2016	0.3	0.2	0.3
	SC	ES/SAF/FAS	Right	VISIT 8	12JUL2017	0.2	0.2	0.3
	SC	ES/SAF/FAS	Right	VISIT 11	03JUN2020	0.2	0.2	3.1
13/1304	ND basic	ES/SAF/FAS	Left	BASELINE (VISIT 2A)	01JUL2015	0.2	7	0.3
	ND basic	ES/SAF/FAS	Left	VISIT 5	14DEC2015	0.3	0.9	0.2
	ND basic	ES/SAF/FAS	Left	VISIT 6	21MAR2016	0.2	0.3	0.3
	ND basic	ES/SAF/FAS	Left	VISIT 7	14SEP2016	0.2	2.4	0.2
	ND basic	ES/SAF/FAS	Left	VISIT 8	06SEP2017	0.3	1.3	0.2
	ND basic	ES/SAF/FAS	Left	VISIT 11	02SEP2020	0.2	0.3	0.3
13/1305	ND plus	ES/SAF	Right	BASELINE (VISIT 2A)	13OCT2015	6.7	0.3	8.5

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0103	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Very few deficits (4)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
					Nerve root L4		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				2000
			Baseline (Visit 2a)	Motor deficits	Ankle flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Very few deficits (4)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
					Nerve root L4		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				2000

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0103	NDisc basic	ES/SAF/FAS	Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Very few deficits (4)	
			Visit 4	Cauda equina syndrome				N
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				800
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0103	NDisc basic ES/SAF/FAS	Visit 5		Sensory deficits	Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				UKN
		Visit 6		Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Nerve root L5		Partial sensory deficit	
				Quality				Intermittent
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				200
		Visit 7		Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0103	NDisc basic	ES/SAF/FAS	Visit 7	Sensory deficits	Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				~200
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Complete sensory deficit	
					Numb nerve roots		Always	
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				0600
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0103	NDisc basic	ES/SAF/FAS	Visit 11	Motor deficits	Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Numb nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				500

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0104	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0104	NDisc basic	ES/SAF/FAS	Visit 3a	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 3k	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0104	NDisc basic	ES/SAF/FAS	Visit 4	Sensory deficits	Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0104	NDisc basic	ES/SAF/FAS	Visit 6	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0104	NDisc basic	ES/SAF/FAS	Visit 7	Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0104	NDisc basic	ES/SAF/FAS	Visit 11	Sensory deficits	Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0106	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots		Always	
					Numb nerve roots		Always	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0106	NDisc plus	ES/SAF/FAS	Visit 3a	Walking range(m)				5000
			Visit 3k	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				5000
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0106	NDisc plus	ES/SAF/FAS	Visit 4	Sensory deficits	Nerve root L2 Nerve root L1	None None	None None	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0106	NDisc plus	ES/SAF/FAS	Visit 6	Motor deficits	Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriiceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test				
						Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriiceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Walking range(m)				unlimited
				Visit 8				
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0106	NDisc plus	ES/SAF/FAS	Visit 8	Motor deficits	Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0106	NDisc plus	ES/SAF/FAS	Visit 11	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0107	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L4		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				100
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0107	NDisc plus	ES/SAF/FAS	Visit 3a	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 3k	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0107	NDisc plus	ES/SAF/FAS	Visit 4	Sensory deficits	Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				5000
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Intermittent	
					Reflexes	Ankle reflex	Reduced	Reduced
						Quadriceps reflex	Normal	Normal
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0107	NDisc plus	ES/SAF/FAS	Visit 6	Sensory deficits	Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0107	NDisc plus	ES/SAF/FAS	Visit 7	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Reduced	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0107	NDisc plus	ES/SAF/FAS	Visit 11	Sensory deficits	Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Reduced	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0108	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0108	NDisc plus	ES/SAF/FAS	Visit 3a	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 3k	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0108	NDisc plus	ES/SAF/FAS	Visit 4	Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive	Positive	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0108	NDisc plus	ES/SAF/FAS	Visit 6	Sensory deficits	Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
					Quality	Tingle nerve roots		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0108	NDisc plus	ES/SAF/FAS	Visit 8	Quality	Tingle nerve roots	Intermittent		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0110	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	Few deficits (3)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				100
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0110	NDisc basic ES/SAF/FAS		Visit 3a	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 3k	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0110	NDisc basic	ES/SAF/FAS	Visit 4	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Negative
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Negative
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0110	NDisc basic ES/SAF/FAS	Visit 6	Motor deficits		Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
		Visit 7	Motor deficits		Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Sensory deficits		Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0110	NDisc basic	ES/SAF/FAS	Visit 7	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0110	NDisc basic ES/SAF/FAS		Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0111	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Tingle nerve roots	Intermittent		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				2000
			Visit 3k	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0111	NDisc plus	ES/SAF/FAS	Visit 3k	Motor deficits	Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	Intermittent		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0111	NDisc plus	ES/SAF/FAS	Visit 4	Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				1000
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0111	NDisc plus	ES/SAF/FAS	Visit 6	Motor deficits	Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Hypersensitive nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Reduced Normal	Normal Normal	
				Cauda equina syndrome			N	
				Sciatic stretch test	Negative	Negative		
				Walking range(m)			Unlimited	
			Visit 7	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1 Nerve root S2 Nerve root L5 Nerve root L4 Nerve root L3 Nerve root L2 Nerve root L1	None None None None None None None	None None None None None None None	
				Quality	Tingle nerve roots Numb nerve roots Hypersensitive nerve roots	None None None	None None None	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome			N	
				Sciatic stretch test	Negative	Negative		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0111	NDisc plus	ES/SAF/FAS	Visit 7	Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General				
01-0111	NDisc plus	ES/SAF/FAS	Visit 11	Sensory deficits	Nerve root L2	None	None					
					Nerve root L1	None	None					
				Quality	Tingle nerve roots	None	None					
					Numb nerve roots	None	None					
					Hypersensitive nerve roots	None	None					
				Reflexes	Ankle reflex	Normal	Normal					
					Quadriiceps reflex	Normal	Normal					
				Cauda equina syndrome					N			
				Sciatic stretch test					Negative	Negative		
				Walking range(m)					Unlimited			

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General			
01-0112	NDisc basic	ES/SAF	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
				Sensory deficits	Nerve root S1		Partial sensory deficit				
					Tingle nerve roots		Intermittent				
					Reflexes	Ankle reflex	Normal	Normal			
				Quadriceps reflex		Normal	Normal				
				Cauda equina syndrome							N
				Sciatic stretch test							Positive
				Walking range(m)							Unlimited
				Unschedule d	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
			Ankle extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Hip flexor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Knee extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Big toe extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Sensory deficits		Nerve root S1		Partial sensory deficit				
					Numb nerve roots		Intermittent				
					Reflexes	Ankle reflex	Normal	Absent			
			Quadriceps reflex			Normal	Normal				
			Cauda equina syndrome								N
			Sciatic stretch test								Positive
			Walking range(m)								unlimited
			Visit 11		Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
				Ankle extensor		No deficits (Normal - 5)	No deficits (Normal - 5)				

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0112	NDisc basic ES/SAF		Visit 11	Motor deficits	Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit	Partial sensory deficit	
				Quality	Tingle nerve roots	Intermittent	Intermittent	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0113	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				300
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Tingle nerve roots	Intermittent		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General	
01-0113	NDisc basic	ES/SAF/FAS	Unscheduled	Motor deficits	Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	Partial sensory deficit			
					Quality	Tingle nerve roots	Intermittent		
					Reflexes	Ankle reflex	Normal	Normal	
				Quadriceps reflex		Normal	Normal		
				Cauda equina syndrome				N	
				Sciatic stretch test		Negative	Negative		
				Walking range(m)				Unlimited	
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Sensory deficits	Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Nerve root S1	Partial sensory deficit			
				Quality	Tingle nerve roots	Intermittent			
				Reflexes	Ankle reflex	Normal	Normal		
					Quadriceps reflex	Normal	Normal		
				Cauda equina syndrome				N	
			Visit 5	Motor deficits	Sciatic stretch test	Negative	Negative		
					Walking range(m)			Unlimited	
					Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					</				

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0113	NDisc basic	ES/SAF/FAS	Visit 5	Motor deficits	Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Tingle nerve roots	Intermittent		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0113	NDisc basic	ES/SAF/FAS	Visit 6	Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				1000
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Nerve root L5	Partial sensory deficit		
				Quality	Tingle nerve roots	Always		
					Numb nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0113	NDisc basic	ES/SAF/FAS	Visit 7	Walking range(m)				0100
			Unscheduled	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Few deficits (3)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Nerve root L5	Partial sensory deficit		
				Quality	Tingle nerve roots	Always		
					Numb nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				0100
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0113	NDisc basic	ES/SAF/FAS	Unscheduled	Quality	Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex Quadriceps reflex	Absent Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex Quadriceps reflex	Reduced Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive	Positive	
				Walking range(m)				0010

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0113	NDisc basic ES/SAF/FAS	Visit 8	Motor deficits		Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
		Visit 11	Motor deficits		Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Sensory deficits		Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0113	NDisc basic	ES/SAF/FAS	Visit 11	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0114	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				20
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Intermittent		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 3k	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0114	NDisc basic	ES/SAF/FAS	Visit 3k	Motor deficits	Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Tingle nerve roots	Intermittent		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Exaggerated	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0114	NDisc basic	ES/SAF/FAS	Visit 4	Walking range(m)				Unlimited
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Visit 5		Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Hypersensitive nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0114	NDisc basic	ES/SAF/FAS	Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0114	NDisc basic	ES/SAF/FAS	Visit 11	Motor deficits	Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Reduced Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General	
01-0115	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Sensory deficits	Nerve root L5	Partial sensory deficit	Partial sensory deficit		
					Quality	Numb nerve roots	Always	Always	
					Reflexes	Ankle reflex Quadriceps reflex	Absent Reduced	Absent Absent	
				Cauda equina syndrome					N
				Sciatic stretch test		Negative	Negative		
				Walking range(m)					Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Quality	Tingle nerve roots	Intermittent	Intermittent		
					Reflexes	Ankle reflex Quadriceps reflex	Reduced Reduced	Reduced Reduced	
					Cauda equina syndrome				
				Sciatic stretch test		Negative	Negative		
				Walking range(m)					Unlimited
				Visit 3k	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Ankle extensor			No deficits (Normal - 5)	No deficits (Normal - 5)		
			Hip flexor			No deficits (Normal - 5)	No deficits (Normal - 5)		
			Knee extensor			No deficits (Normal - 5)	No deficits (Normal - 5)		
			Big toe extensor			No deficits (Normal - 5)	No deficits (Normal - 5)		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0115	NDisc plus	ES/SAF/FAS	Visit 3k	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0115	NDisc plus	ES/SAF/FAS	Visit 4	Sciatic stretch test		Negative	Negative	
				Walking range(m)				>=5000
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex Quadriceps reflex	Reduced Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0115	NDisc plus	ES/SAF/FAS	Visit 6	Reflexes	Ankle reflex Quadriceps reflex	Reduced Reduced	Reduced Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0115	NDisc plus	ES/SAF/FAS	Visit 8	Motor deficits	Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriiceps reflex	Absent	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0115	NDisc plus	ES/SAF/FAS	Visit 11	Quality	Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0116	NDisc basic ES/SAF		Baseline (Visit 2a)	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriiceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				500

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0118	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Complete sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				1000
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 3k	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0118	NDisc plus	ES/SAF/FAS	Visit 3k	Motor deficits	Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Reduced Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Absent Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0118	NDisc plus	ES/SAF/FAS	Visit 5	Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Negative
				Walking range(m)				3000
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0118	NDisc plus	ES/SAF/FAS	Unscheduled	Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Absent Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex Quadriceps reflex	Absent Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0118	NDisc plus	ES/SAF/FAS	Unschedule d	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality	Numb nerve roots		
					Reflexes	Ankle reflex Quadriceps reflex	Absent Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative		
				Walking range(m)				1000
			Unschedule d	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality	Numb nerve roots		
					Reflexes	Ankle reflex Quadriceps reflex	Absent Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)		No deficits (Normal - 5)

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0118	NDisc plus	ES/SAF/FAS	Visit 7	Motor deficits	Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality			
					Tingle nerve roots	Always		
					Numb nerve roots	Always		
					Hypersensitive nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Exaggerated	Exaggerated	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive	Positive	
				Walking range(m)				1000
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality			
					Numb nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0118	NDisc plus	ES/SAF/FAS	Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0118	NDisc plus	ES/SAF/FAS	Unscheduled	Sensory deficits	Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Unscheduled	Motor deficits			
					Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Unscheduled	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
			Unscheduled	Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0118	NDisc plus	ES/SAF/FAS	Unscheduled	Walking range(m)				2000
			Unscheduled	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Nerve root S2	Partial sensory deficit		
					Nerve root L5	Partial sensory deficit		
					Nerve root L4	Partial sensory deficit		
					Nerve root L3	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
			Visit 11	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Knee extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0119	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Complete sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				500
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Intermittent		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 3k	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0119	NDisc basic	ES/SAF/FAS	Visit 3k	Motor deficits	Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Intermittent		
				Reflexes	Ankle reflex Quadriiceps reflex	Reduced Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1 Nerve root S2 Nerve root L5 Nerve root L4 Nerve root L3 Nerve root L2 Nerve root L1	None None None None None None None	None None None None None None None	
				Quality	Tingle nerve roots Numb nerve roots Hypersensitive nerve roots	None None None	None None None	
				Reflexes	Ankle reflex Quadriiceps reflex	Reduced Reduced	Reduced Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0119	NDisc basic	ES/SAF/FAS	Visit 4	Walking range(m)				Unlimited
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Visit 5		Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Tingle nerve roots	Intermittent		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Hypersensitive nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Absent	
					Quadriciceps reflex	Absent	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0119	NDisc basic	ES/SAF/FAS	Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				8000
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality	Numb nerve roots		
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0119	NDisc basic ES/SAF/FAS		Visit 8	Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Reduced Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Nerve root L5	Partial sensory deficit		
				Quality	Tingle nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				2000

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0121	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				~500
			Baseline (Visit 2a)	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0121	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Sensory deficits	Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
			Visit 3a	Sciatic stretch test			Positive	
				Walking range(m)				~500
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
			Visit 3a	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0121	NDisc plus	ES/SAF/FAS	Visit 3a	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 3k	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriiceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				3000
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0121	NDisc plus	ES/SAF/FAS	Visit 4	Sensory deficits	Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriiceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
			Visit 5	Sciatic stretch test		Negative	Negative	3000
				Walking range(m)				
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Visit 5	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
			Visit 5	Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0121	NDisc plus	ES/SAF/FAS	Visit 5	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0121	NDisc plus	ES/SAF/FAS	Visit 7	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriiceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0121	NDisc plus	ES/SAF/FAS	Visit 8	Reflexes	Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0122	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				500
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 3k	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General		
01-0122	NDisc plus	ES/SAF/FAS	Visit 3k	Motor deficits	Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
				Sensory deficits	Nerve root S1	Partial sensory deficit				
					Quality	Numb nerve roots				
					Reflexes	Ankle reflex	Normal		Reduced	
					Quadriceps reflex	Normal	Normal			
				Cauda equina syndrome			N			
				Sciatic stretch test	Negative	Negative				
				Walking range(m)			Unlimited			
				Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)		No deficits (Normal - 5)	
						Ankle extensor	No deficits (Normal - 5)		No deficits (Normal - 5)	
						Hip flexor	No deficits (Normal - 5)		No deficits (Normal - 5)	
						Knee extensor	No deficits (Normal - 5)		No deficits (Normal - 5)	
			Big toe extensor			No deficits (Normal - 5)	No deficits (Normal - 5)			
			Sensory deficits		Nerve root S1	Partial sensory deficit				
					Quality	Numb nerve roots				
					Reflexes	Ankle reflex	Reduced	Normal		
					Quadriceps reflex	Normal	Normal			
			Cauda equina syndrome				N			
			Sciatic stretch test		Negative	Negative				
			Walking range(m)				Unlimited			
			Visit 5		Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
						Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Hip flexor		No deficits (Normal - 5)	No deficits (Normal - 5)			
				Knee extensor		No deficits (Normal - 5)	No deficits (Normal - 5)			
				Big toe extensor		No deficits (Normal - 5)	No deficits (Normal - 5)			

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0122	NDisc plus	ES/SAF/FAS	Visit 5	Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Absent Normal	Reduced Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Absent Reduced	Reduced Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Absent Reduced	Reduced Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0122	NDisc plus	ES/SAF/FAS	Visit 7	Reflexes	Ankle reflex Quadriceps reflex	Absent Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex Quadriceps reflex	Absent Normal	Normal Normal
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0122	NDisc plus	ES/SAF/FAS	Unscheduled	Sensory deficits	Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Absent	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				2000
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality	Numb nerve roots	Always	
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Negative
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0123	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
					Quality		Numb nerve roots	
					Reflexes		Ankle reflex Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				1000
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
					Quality		Numb nerve roots	
					Reflexes		Ankle reflex Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0123	NDisc plus	ES/SAF/FAS	Visit 4	Motor deficits	Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex Quadriiceps reflex	Normal Normal	Normal Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				0500
			Visit 5	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots		Always	
				Reflexes	Ankle reflex Quadriiceps reflex	Reduced Reduced	Reduced Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0123	NDisc plus	ES/SAF/FAS	Visit 6	Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex Quadriceps reflex	Reduced Reduced	Reduced Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots Hypersensitive nerve roots		Always Always	
				Reflexes	Ankle reflex Quadriceps reflex	Reduced Reduced	Reduced Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				1500
			Visit 8	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit	Partial sensory deficit	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0123	NDisc plus	ES/SAF/FAS	Visit 8	Quality	Numb nerve roots	Always	Always	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
		Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	Very few deficits (4)		
				Ankle extensor	No deficits (Normal - 5)	Few deficits (3)		
				Hip flexor				
				Knee extensor	No deficits (Normal - 5)	Very few deficits (4)		
				Big toe extensor	No deficits (Normal - 5)	Many deficits (2)		
			Sensory deficits	Nerve root S1	None	None		
				Nerve root S2	None	None		
				Nerve root L5	None	None		
				Nerve root L4	None	None		
				Nerve root L3	None	None		
				Nerve root L2	None	None		
				Nerve root L1	None	None		
			Quality	Tingle nerve roots	None	None		
				Numb nerve roots	None	None		
				Hypersensitive nerve roots	None	None		
			Walking range(m)					UNK

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0124	NDisc plus	ES/SAF	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Baseline (Visit 2a)	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0124	NDisc plus	ES/SAF	Baseline (Visit 2a)	Sensory deficits	Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0125	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0125	SC	ES/SAF/FAS	Visit 4	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriiceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0125	SC	ES/SAF/FAS	Visit 6	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0125	SC	ES/SAF/FAS	Visit 7	Reflexes	Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				Y
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
		Unscheduled	Motor deficits		Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0125	SC	ES/SAF/FAS	Unscheduled	Motor deficits	Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	Intermittent		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				ND
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0125	SC	ES/SAF/FAS	Visit 11	Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0126	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Hypersensitive nerve roots	Intermittent		
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriiceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0126	NDisc basic	ES/SAF/FAS	Visit 4	Motor deficits	Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0126	NDisc basic	ES/SAF/FAS	Unscheduled	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				0500
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0126	NDisc basic ES/SAF/FAS	Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
			Sensory deficits	Nerve root S1	None	None		
				Nerve root S2	None	None		
				Nerve root L5	None	None		
				Nerve root L4	None	None		
				Nerve root L3	None	None		
				Nerve root L2	None	None		
				Nerve root L1	None	None		
			Quality	Tingle nerve roots	None	None		
				Numb nerve roots	None	None		
				Hypersensitive nerve roots	None	None		
			Reflexes	Ankle reflex	Normal	Normal		
				Quadriceps reflex	Normal	Normal		
			Cauda equina syndrome					N
			Sciatic stretch test		Negative	Negative		
			Walking range(m)					Unlimited
		Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
			Sensory deficits	Nerve root S1	None	None		
				Nerve root S2	None	None		
				Nerve root L5	None	None		
				Nerve root L4	None	None		
				Nerve root L3	None	None		
				Nerve root L2	None	None		
				Nerve root L1	None	None		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0126	NDisc basic	ES/SAF/FAS	Visit 7	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Absent	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0126	NDisc basic	ES/SAF/FAS	Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0127	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Negative
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0127	NDisc plus	ES/SAF/FAS	Visit 4	Motor deficits	Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Absent Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Reduced Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0127	NDisc plus	ES/SAF/FAS	Visit 6	Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex Quadriceps reflex	Reduced Reduced	Reduced Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0127	NDisc plus	ES/SAF/FAS	Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0127	NDisc plus	ES/SAF/FAS	Unscheduled	Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0128	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Very few deficits (4)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0128	NDisc plus	ES/SAF/FAS	Visit 3a	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0128	NDisc plus	ES/SAF/FAS	Visit 5	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Absent	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0128	NDisc plus	ES/SAF/FAS	Visit 6	Reflexes	Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General		
01-0128	NDisc plus	ES/SAF/FAS	Visit 8	Sensory deficits	Nerve root S1	None	None			
					Nerve root S2	None	None			
					Nerve root L5	None	None			
					Nerve root L4	None	None			
					Nerve root L3	None	None			
					Nerve root L2	None	None			
					Nerve root L1	None	None			
				Quality	Tingle nerve roots	None	None			
					Numb nerve roots	None	None			
					Hypersensitive nerve roots	None	None			
				Reflexes	Ankle reflex	Normal	Reduced			
					Quadriceps reflex	Normal	Normal			
				Cauda equina syndrome					N	
				Sciatic stretch test					Negative	Negative
				Walking range(m)					Unlimited	
				Unschedule d	Motor deficits	Ankle flexor	No deficits (Normal - 5)		No deficits (Normal - 5)	
						Ankle extensor	No deficits (Normal - 5)		No deficits (Normal - 5)	
						Hip flexor	No deficits (Normal - 5)		No deficits (Normal - 5)	
						Knee extensor	No deficits (Normal - 5)		No deficits (Normal - 5)	
						Big toe extensor	No deficits (Normal - 5)		No deficits (Normal - 5)	
					Sensory deficits	Nerve root S1	None		None	
						Nerve root S2	None		None	
						Nerve root L5	None		None	
						Nerve root L4	None		None	
			Nerve root L3			None	None			
			Nerve root L2			None	None			
			Nerve root L1			None	None			
			Quality		Numb nerve roots	Always				
			Cauda equina syndrome				N			

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0128	NDisc plus	ES/SAF/FAS	Unscheduled	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0129	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	Many deficits (2)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Many deficits (2)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				0500
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	Many deficits (2)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Many deficits (2)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots		Always	
					Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	Many deficits (2)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0129	SC	ES/SAF/FAS	Visit 5	Motor deficits	Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) Many deficits (2)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots Numb nerve roots		Intermittent Intermittent	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) Few deficits (3) No deficits (Normal - 5) No deficits (Normal - 5) Few deficits (3)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Reduced	Normal Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	Very few deficits (4) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0129	SC	ES/SAF/FAS	Visit 7	Motor deficits	Big toe extensor	No deficits (Normal - 5)		Few deficits (3)
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots Numb nerve roots		Intermittent Intermittent	
				Reflexes	Ankle reflex Quadriceps reflex	Reduced Reduced	Reduced Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) Very few deficits (4)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Intermittent	
				Reflexes	Ankle reflex Quadriceps reflex	Reduced Reduced	Reduced Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) Few deficits (3) No deficits (Normal - 5) No deficits (Normal - 5) Few deficits (3)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0129	SC	ES/SAF/FAS	Unscheduled	Sensory deficits	Nerve root L5		Partial sensory deficit	
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	Very few deficits (4)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Few deficits (3)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0130	NDisc basic ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
			Sensory deficits	Nerve root S1	None	None		
				Nerve root S2	None	None		
				Nerve root L5	None	None		
				Nerve root L4	None	None		
				Nerve root L3	None	None		
				Nerve root L2	None	None		
				Nerve root L1	None	None		
			Quality	Tingle nerve roots	None	None		
				Numb nerve roots	None	None		
				Hypersensitive nerve roots	None	None		
			Reflexes	Ankle reflex	Normal	Normal		
				Quadriceps reflex	Normal	Normal		
			Cauda equina syndrome					N
			Sciatic stretch test		Positive			
			Walking range(m)					0600
		Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
			Sensory deficits	Nerve root S1	None	None		
				Nerve root S2	None	None		
				Nerve root L5	None	None		
				Nerve root L4	None	None		
				Nerve root L3	None	None		
				Nerve root L2	None	None		
				Nerve root L1	None	None		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0130	NDisc basic ES/SAF/FAS	Visit 3a	Quality		Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
			Reflexes		Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
			Cauda equina syndrome					
			Sciatic stretch test			Negative	Negative	
			Walking range(m)					
		Visit 4	Motor deficits		Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Sensory deficits		Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
			Quality		Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
			Reflexes		Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
			Cauda equina syndrome					
			Sciatic stretch test			Negative	Negative	
			Walking range(m)					

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0130	NDisc basic ES/SAF/FAS	Visit 5	Motor deficits		Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
		Visit 6	Motor deficits		Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Sensory deficits		Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0130	NDisc basic	ES/SAF/FAS	Visit 6	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0130	NDisc basic ES/SAF/FAS	Visit 8	Motor deficits		Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
		Visit 11	Motor deficits		Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Sensory deficits		Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0130	NDisc basic	ES/SAF/FAS	Visit 11	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0131	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
					Tingle nerve roots		Intermittent	
					Ankle reflex		Normal	
				Reflexes	Quadiceps reflex		Normal	
					Cauda equina syndrome		N	
				Sciatic stretch test		Positive		
				Walking range(m)				50
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
					Numb nerve roots		Intermittent	
					Ankle reflex		Normal	
				Reflexes	Quadiceps reflex		Normal	
					Cauda equina syndrome		N	
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0131	NDisc plus	ES/SAF/FAS	Visit 4	Motor deficits	Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0131	NDisc plus	ES/SAF/FAS	Visit 6	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
					Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0131	NDisc plus	ES/SAF/FAS	Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0132	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0132	SC	ES/SAF/FAS	Visit 4	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0132	SC	ES/SAF/FAS	Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0132	SC	ES/SAF/FAS	Visit 7	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0132	SC	ES/SAF/FAS	Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0133	NDisc plus	ES/SAF	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				500
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0133	NDisc plus	ES/SAF	Unscheduled	Sensory deficits	Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Normal	
					Quadiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				500

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General				
01-0134	NDisc basic ES/SAF		Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)					
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)					
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)					
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)					
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)					
				Sensory deficits	Nerve root S1	Partial sensory deficit						
				Quality	Numb nerve roots	Always						
				Reflexes	Ankle reflex	Normal	Normal					
					Quadriceps reflex	Normal	Normal					
				Cauda equina syndrome								
				Sciatic stretch test						Positive		
				Walking range(m)								Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0135	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex Quadriciceps reflex	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Intermittent	
					Reflexes	Ankle reflex Quadriciceps reflex	Reduced Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Negative
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0135	NDisc plus	ES/SAF/FAS	Visit 4	Motor deficits	Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Numb nerve roots		Intermittent	
				Reflexes	Ankle reflex Quadriceps reflex	Reduced Normal	Reduced Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Absent Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0135	NDisc plus	ES/SAF/FAS	Visit 6	Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex Quadriciceps reflex	Normal Normal	Absent Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0135	NDisc plus	ES/SAF/FAS	Visit 8	Motor deficits	Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0135	NDisc plus	ES/SAF/FAS	Visit 11	Quality	Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General			
01-0136	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
				Sensory deficits	Nerve root L4		Partial sensory deficit				
					Numb nerve roots		Always				
					Reflexes	Ankle reflex	Normal	Normal			
				Quadriceps reflex		Normal	Normal				
				Cauda equina syndrome							N
				Sciatic stretch test							Positive
				Walking range(m)							Unlimited
				Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
			Ankle extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Hip flexor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Knee extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Big toe extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Sensory deficits		Nerve root L5		Partial sensory deficit				
					Tingle nerve roots		Always				
					Reflexes	Ankle reflex	Normal	Normal			
			Quadriceps reflex			Absent	Absent				
			Cauda equina syndrome								N
			Sciatic stretch test								Negative
			Walking range(m)								2000
			Visit 4		Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
				Ankle extensor		No deficits (Normal - 5)	No deficits (Normal - 5)				
				Hip flexor		No deficits (Normal - 5)	No deficits (Normal - 5)				

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0136	NDisc basic	ES/SAF/FAS	Visit 4	Motor deficits	Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriciceps reflex	Absent	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L3		Complete sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0136	NDisc basic	ES/SAF/FAS	Visit 5	Walking range(m)				1000
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L3		Complete sensory deficit	
				Quality	Numb nerve roots Hypersensitive nerve roots		Always Intermittent	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				1000
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L4 Nerve root L3		Partial sensory deficit Complete sensory deficit	
				Quality	Tingle nerve roots Hypersensitive nerve roots		Always Always	
				Reflexes	Ankle reflex Quadriceps reflex	Absent Reduced	Absent Reduced	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0136	NDisc basic	ES/SAF/FAS	Visit 6	Sciatic stretch test		Negative	Negative	
				Walking range(m)				1000
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L4		Partial sensory deficit	
				Quality	Tingle nerve roots		Always	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Absent	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				500

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0136	NDisc basic	ES/SAF/FAS	Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
					Quality		Tingle nerve roots	Always
					Reflexes		Ankle reflex Quadiceps reflex	Normal Normal
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				200

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General			
01-0137	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	Few deficits (3)	No deficits (Normal - 5)				
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Big toe extensor	Few deficits (3)	No deficits (Normal - 5)				
				Sensory deficits	Nerve root L5	Partial sensory deficit					
					Quality	Numb nerve roots	Always				
					Reflexes	Ankle reflex	Reduced	Reduced			
				Quadriceps reflex		Normal	Normal				
				Cauda equina syndrome							N
				Sciatic stretch test	Positive						
				Walking range(m)							1500
				Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
			Ankle extensor			Very few deficits (4)	No deficits (Normal - 5)				
			Hip flexor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Knee extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Big toe extensor			Few deficits (3)	No deficits (Normal - 5)				
			Sensory deficits		Nerve root S1	None	None				
					Nerve root S2	None	None				
					Nerve root L5	None	None				
					Nerve root L4	None	None				
					Nerve root L3	None	None				
					Nerve root L2	None	None				
					Nerve root L1	None	None				
			Quality		Tingle nerve roots	None	None				
					Numb nerve roots	None	None				
					Hypersensitive nerve roots	None	None				
			Reflexes		Ankle reflex	Reduced	Reduced				
					Quadriceps reflex	Normal	Normal				

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0137	NDisc plus	ES/SAF/FAS	Visit 3a	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0137	NDisc plus	ES/SAF/FAS	Visit 5	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0137	NDisc plus	ES/SAF/FAS	Visit 6	Reflexes	Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0137	NDisc plus	ES/SAF/FAS	Visit 8	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0137	NDisc plus	ES/SAF/FAS	Visit 11	Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0138	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0138	SC	ES/SAF/FAS	Visit 4	Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0138	SC	ES/SAF/FAS	Visit 6	Sensory deficits	Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
			Visit 7	Sciatic stretch test		Negative	Negative	Unlimited
				Walking range(m)				
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Visit 7	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
			Visit 7	Reflexes	Ankle reflex	Normal	Absent	
					Quadriiceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0138	SC	ES/SAF/FAS	Visit 7	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0138	SC	ES/SAF/FAS	Visit 11	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0139	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				0500
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	Intermittent	
					Hypersensitive nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0139	NDisc plus	ES/SAF/FAS	Visit 3a	Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Absent Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Always	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Absent Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0139	NDisc plus	ES/SAF/FAS	Visit 5	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality		Always	
					Reflexes		Reduced	
				Cauda equina syndrome	Ankle reflex		Reduced	
					Quadriceps reflex		Reduced	
			Visit 7	Motor deficits	Cauda equina syndrome		N	
					Sciatic stretch test		Negative	
					Walking range(m)		Unlimited	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality		Always	
					Reflexes		Reduced	
				Cauda equina syndrome	Ankle reflex		Absent	
					Quadriceps reflex		Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0139	NDisc plus	ES/SAF/FAS	Visit 7	Walking range(m)				Unlimited
				Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)
						Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)
						Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)
						Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)
						Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)
					Sensory deficits	Nerve root S1		Partial sensory deficit
					Quality	Numb nerve roots		Always
					Reflexes	Ankle reflex	Reduced	Absent
						Quadriceps reflex	Reduced	Reduced
					Cauda equina syndrome			N
					Sciatic stretch test		Positive	
					Walking range(m)			Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Sensory deficits	Nerve root S1		Partial sensory deficit
					Quality	Numb nerve roots		Always
					Reflexes	Ankle reflex	Reduced	Reduced
						Quadriceps reflex	Reduced	Reduced
					Cauda equina syndrome			N
					Sciatic stretch test	Negative	Negative	
					Walking range(m)			Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0140	NDisc basic ES/SAF/FAS	Visit 1		Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
		Visit 3a	Motor deficits		Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Sensory deficits		Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
			Quality		Tingle nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0140	NDisc basic	ES/SAF/FAS	Visit 3a	Quality	Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
			Visit 4	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0140	NDisc basic ES/SAF/FAS	Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
			Sensory deficits	Nerve root S1	None	None		
				Nerve root S2	None	None		
				Nerve root L5	None	None		
				Nerve root L4	None	None		
				Nerve root L3	None	None		
				Nerve root L2	None	None		
				Nerve root L1	None	None		
			Quality	Tingle nerve roots	None	None		
				Numb nerve roots	None	None		
				Hypersensitive nerve roots	None	None		
			Reflexes	Ankle reflex	Reduced	Reduced		
				Quadriciceps reflex	Normal	Normal		
			Cauda equina syndrome					N
			Sciatic stretch test		Negative	Negative		
			Walking range(m)					Unlimited
		Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
			Sensory deficits	Nerve root S1	None	None		
				Nerve root S2	None	None		
				Nerve root L5	None	None		
				Nerve root L4	None	None		
				Nerve root L3	None	None		
				Nerve root L2	None	None		
				Nerve root L1	None	None		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0140	NDisc basic	ES/SAF/FAS	Visit 6	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0140	NDisc basic ES/SAF/FAS	Visit 8	Motor deficits		Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
		Visit 11	Motor deficits		Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Sensory deficits		Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0140	NDisc basic	ES/SAF/FAS	Visit 11	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General			
01-0141	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
				Sensory deficits	Nerve root S1		Partial sensory deficit				
					Numb nerve roots		Always				
					Reflexes	Ankle reflex	Normal	Absent			
				Quadriceps reflex		Normal	Normal				
				Cauda equina syndrome							N
				Sciatic stretch test							Positive
				Walking range(m)							Unlimited
				Baseline (Visit 2a)	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
			Ankle extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Hip flexor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Knee extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Big toe extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Sensory deficits		Nerve root S1		Partial sensory deficit				
					Numb nerve roots		Always				
					Reflexes	Ankle reflex	Normal	Absent			
			Quadriceps reflex			Normal	Normal				
			Cauda equina syndrome								N
			Sciatic stretch test								Positive
			Walking range(m)								Unlimited
			Visit 4		Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
				Ankle extensor		No deficits (Normal - 5)	No deficits (Normal - 5)				

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0141	SC	ES/SAF/FAS	Visit 4	Motor deficits	Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Negative
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
					Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0141	SC	ES/SAF/FAS	Visit 5	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0141	SC	ES/SAF/FAS	Visit 7	Sensory deficits	Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
			Visit 8	Sciatic stretch test		Negative	Negative	Unlimited
				Walking range(m)				
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Visit 8	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
			Visit 8	Reflexes	Ankle reflex	Normal	Absent	
					Quadriiceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0141	SC	ES/SAF/FAS	Visit 8	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Unschedule d	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General				
01-0141	SC	ES/SAF/FAS	Unscheduled	Sensory deficits	Nerve root S1	None	None					
					Nerve root S2	None	None					
					Nerve root L5	None	None					
					Nerve root L4	None	None					
					Nerve root L3	None	None					
					Nerve root L2	None	None					
					Nerve root L1	None	None					
				Quality	Tingle nerve roots	None	None					
					Numb nerve roots	None	None					
					Hypersensitive nerve roots	None	None					
				Reflexes	Ankle reflex	Normal	Normal					
					Quadriceps reflex	Normal	Normal					
				Cauda equina syndrome					N			
				Sciatic stretch test					Negative		Negative	
				Walking range(m)					Unlimited			

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0142	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Very few deficits (4)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0142	NDisc plus	ES/SAF/FAS	Visit 3a	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Negative
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Negative
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0142	NDisc plus	ES/SAF/FAS	Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0142	NDisc plus	ES/SAF/FAS	Visit 6	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Normal	Normal	
			Visit 7	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0142	NDisc plus	ES/SAF/FAS	Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Reduced	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0142	NDisc plus	ES/SAF/FAS	Visit 11	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0143	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0143	NDisc plus	ES/SAF/FAS	Visit 3a	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0143	NDisc plus	ES/SAF/FAS	Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General		
01-0143	NDisc plus	ES/SAF/FAS	Visit 6	Quality	Tingle nerve roots	None	None			
					Numb nerve roots	None	None			
					Hypersensitive nerve roots	None	None			
				Reflexes	Ankle reflex	Normal	Normal			
					Quadriceps reflex	Normal	Normal			
				Cauda equina syndrome					N	
				Sciatic stretch test					Negative	Negative
				Walking range(m)					Unlimited	
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
				Sensory deficits	Nerve root S1	None	None			
					Nerve root S2	None	None			
					Nerve root L5	None	None			
					Nerve root L4	None	None			
					Nerve root L3	None	None			
					Nerve root L2	None	None			
					Nerve root L1	None	None			
				Quality	Tingle nerve roots	None	None			
					Numb nerve roots	None	None			
					Hypersensitive nerve roots	None	None			
				Reflexes	Ankle reflex	Normal	Normal			
					Quadriceps reflex	Normal	Normal			
				Cauda equina syndrome				N		
				Sciatic stretch test				Negative	Negative	
				Walking range(m)				Unlimited		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0143	NDisc plus	ES/SAF/FAS	Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0143	NDisc plus	ES/SAF/FAS	Visit 11	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0144	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0144	NDisc basic	ES/SAF/FAS	Visit 3a	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General		
01-0144	NDisc basic	ES/SAF/FAS	Visit 5	Sensory deficits	Nerve root S2	None	None			
					Nerve root L5	None	None			
					Nerve root L4	None	None			
					Nerve root L3	None	None			
					Nerve root L2	None	None			
					Nerve root L1	None	None			
				Quality	Tingle nerve roots	None	None			
					Numb nerve roots	None	None			
					Hypersensitive nerve roots	None	None			
				Reflexes	Ankle reflex	Normal	Normal			
					Quadriceps reflex	Normal	Normal			
				Cauda equina syndrome						N
				Sciatic stretch test		Negative	Negative			
				Walking range(m)						Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
				Sensory deficits	Nerve root S1	None	None			
					Nerve root S2	None	None			
					Nerve root L5	None	None			
					Nerve root L4	None	None			
					Nerve root L3	None	None			
					Nerve root L2	None	None			
					Nerve root L1	None	None			
				Quality	Tingle nerve roots	None	None			
					Numb nerve roots	None	None			
					Hypersensitive nerve roots	None	None			
				Reflexes	Ankle reflex	Normal	Normal			

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0144	NDisc basic ES/SAF/FAS		Visit 6	Reflexes	Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General		
01-0144	NDisc basic	ES/SAF/FAS	Visit 8	Sensory deficits	Nerve root S1	None	None			
					Nerve root S2	None	None			
					Nerve root L5	None	None			
					Nerve root L4	None	None			
					Nerve root L3	None	None			
					Nerve root L2	None	None			
					Nerve root L1	None	None			
				Quality	Tingle nerve roots	None	None			
					Numb nerve roots	None	None			
					Hypersensitive nerve roots	None	None			
				Reflexes	Ankle reflex	Reduced	Normal			
					Quadriceps reflex	Normal	Normal			
				Cauda equina syndrome						N
				Sciatic stretch test			Negative	Negative		
				Walking range(m)					Unlimited	
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)		No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	None	None			
					Nerve root S2	None	None			
					Nerve root L5	None	None			
					Nerve root L4	None	None			
					Nerve root L3	None	None			
					Nerve root L2	None	None			
					Nerve root L1	None	None			
				Quality	Tingle nerve roots	None	None			
					Numb nerve roots	None	None			
					Hypersensitive nerve roots	None	None			

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0144	NDisc basic	ES/SAF/FAS	Unscheduled	Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
				Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
			Visit 11	Quality	Tingle nerve roots	Intermittent		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
				Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0144	NDisc basic	ES/SAF/FAS	Visit 11	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0145	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0145	NDisc plus	ES/SAF/FAS	Unscheduled	Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0145	NDisc plus	ES/SAF/FAS	Visit 4	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0145	NDisc plus	ES/SAF/FAS	Visit 5	Reflexes	Ankle reflex Quadriceps reflex	Reduced Reduced	Reduced Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0145	NDisc plus	ES/SAF/FAS	Visit 7	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0145	NDisc plus	ES/SAF/FAS	Visit 11	Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0146	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		None	
					Nerve root S2		None	
					Nerve root L5		None	
					Nerve root L4		None	
					Nerve root L3		None	
					Nerve root L2		None	
					Nerve root L1		None	
				Quality	Tingle nerve roots		None	
					Numb nerve roots		None	
					Hypersensitive nerve roots		None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0146	SC	ES/SAF/FAS	Visit 4	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0146	SC	ES/SAF/FAS	Visit 6	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0146	SC	ES/SAF/FAS	Visit 7	Reflexes	Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Intermittent		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0146	SC	ES/SAF/FAS	Visit 11	Quality	Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0147	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Absent	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0147	NDisc plus	ES/SAF/FAS	Visit 3a	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Absent	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Absent	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0147	NDisc plus	ES/SAF/FAS	Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Absent	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0147	NDisc plus	ES/SAF/FAS	Visit 6	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Absent	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Absent	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0147	NDisc plus	ES/SAF/FAS	Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0147	NDisc plus	ES/SAF/FAS	Visit 11	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0148	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				0100
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Hypersensitive nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0148	NDisc plus	ES/SAF/FAS	Visit 4	Motor deficits	Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0148	NDisc plus	ES/SAF/FAS	Visit 5	Quality	Numb nerve roots Hypersensitive nerve roots	None None	None None	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots Hypersensitive nerve roots		Intermittent Intermittent	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Absent Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0148	NDisc plus	ES/SAF/FAS	Visit 7	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0148	NDisc plus	ES/SAF/FAS	Visit 8	Reflexes	Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0148	NDisc plus	ES/SAF/FAS	Visit 11	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0149	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0149	NDisc plus	ES/SAF/FAS	Visit 3a	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0149	NDisc plus	ES/SAF/FAS	Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0149	NDisc plus	ES/SAF/FAS	Visit 6	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0149	NDisc plus	ES/SAF/FAS	Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0149	NDisc plus	ES/SAF/FAS	Visit 11	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0150		ES	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L4	Partial sensory deficit		
				Quality	Tingle nerve roots	Always		
					Hypersensitive nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General		
01-0151	NDisc basic ES/SAF/FAS		Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
				Sensory deficits	Nerve root S1	None	None			
					Nerve root S2	None	None			
					Nerve root L5	None	None			
					Nerve root L4	None	None			
					Nerve root L3	None	None			
					Nerve root L2	None	None			
					Nerve root L1	None	None			
				Quality	Tingle nerve roots	None	None			
					Numb nerve roots	None	None			
					Hypersensitive nerve roots	None	None			
				Reflexes	Ankle reflex	Normal	Reduced			
					Quadriceps reflex	Normal	Normal			
				Cauda equina syndrome				N		
				Sciatic stretch test				Positive		
				Walking range(m)				0100		
				Visit 3a			Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)
			Ankle extensor					No deficits (Normal - 5)	No deficits (Normal - 5)	
			Hip flexor					No deficits (Normal - 5)	No deficits (Normal - 5)	
			Knee extensor					No deficits (Normal - 5)	No deficits (Normal - 5)	
			Big toe extensor					No deficits (Normal - 5)	No deficits (Normal - 5)	
			Sensory deficits				Nerve root S1		Partial sensory deficit	
Quality	Numb nerve roots		Intermittent							
Reflexes	Ankle reflex	Normal	Reduced							
	Quadriceps reflex	Normal	Normal							

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0151	NDisc basic	ES/SAF/FAS	Visit 3a	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Intermittent	
					Reflexes	Ankle reflex Quadriceps reflex	Reduced Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex Quadriceps reflex	Absent Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0151	NDisc basic	ES/SAF/FAS	Visit 5	Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0151	NDisc basic	ES/SAF/FAS	Visit 7	Sensory deficits	Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0151	NDisc basic ES/SAF/FAS		Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0152	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Tingle nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0152	SC	ES/SAF/FAS	Visit 4	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality		Tingle nerve roots	
					Reflexes		Ankle reflex Quadriceps reflex	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1		Complete sensory deficit	
					Quality		Tingle nerve roots	
					Reflexes		Ankle reflex Quadriceps reflex	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0152	SC	ES/SAF/FAS	Visit 6	Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality	Intermittent		
					Reflexes	Ankle reflex Quadriiceps reflex	Absent Normal	Normal Normal
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
					Quality	Numb nerve roots		
					Reflexes	Ankle reflex Quadriiceps reflex	Normal Normal	Normal Normal
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0152	SC	ES/SAF/FAS	Visit 11	Motor deficits	Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Numb nerve roots	Intermittent		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0153	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0153	NDisc basic	ES/SAF/FAS	Visit 3a	Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0153	NDisc basic	ES/SAF/FAS	Visit 4	Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				2000
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0153	NDisc basic ES/SAF/FAS		Visit 6	Motor deficits	Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0153	NDisc basic	ES/SAF/FAS	Visit 7	Quality	Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
		Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
01-0153	NDisc basic	ES/SAF/FAS	Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0201	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				>1000
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0201	NDisc plus	ES/SAF/FAS	Visit 3k	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
						Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0201	NDisc plus	ES/SAF/FAS	Visit 4	Sciatic stretch test		Negative	Negative	
				Walking range(m)				>1000
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				<1000
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0201	NDisc plus	ES/SAF/FAS	Visit 6	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive	Positive	
				Walking range(m)				1000
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0201	NDisc plus	ES/SAF/FAS	Visit 8	Motor deficits	Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		Very few deficits (4)
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriciceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0201	NDisc plus	ES/SAF/FAS	Unscheduled	Sciatic stretch test			Positive	
				Walking range(m)				1000
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0202	NDisc basic ES/SAF		Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
					Quality	Numb nerve roots		
				Reflexes	Ankle reflex	Absent	Reduced	
					Quadiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				5

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0203	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L4	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Absent	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				10
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L4	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				>3000
			Visit 3k	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	Very few deficits (4)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0203	NDisc basic ES/SAF/FAS		Visit 3k	Motor deficits	Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L4	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriiceps reflex	Normal Reduced	Normal Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				1000
			Visit 4	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5 Nerve root L4	Partial sensory deficit Partial sensory deficit		
				Reflexes	Ankle reflex Quadriiceps reflex	Reduced Absent	Reduced Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				1500
			Visit 5	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0203	NDisc basic	ES/SAF/FAS	Visit 5	Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Absent	Absent	
				Cauda equina syndrome				N
				Walking range(m)				>1000
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Tingle nerve roots	Intermittent		
					Numb nerve roots	Intermittent		
					Hypersensitive nerve roots	Intermittent		
				Cauda equina syndrome				N
				Walking range(m)				<2000
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General	
02-0203	NDisc basic	ES/SAF/FAS	Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)	Very few deficits (4)		
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Sensory deficits	Nerve root L5	Partial sensory deficit			
					Quality	Numb nerve roots	Always		
					Reflexes	Ankle reflex Quadriceps reflex	Normal Absent	Normal Absent	
				Cauda equina syndrome				N	
				Sciatic stretch test			Positive		
				Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
						Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
						Hip flexor	Very few deficits (4)	No deficits (Normal - 5)	
						Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
						Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Sensory deficits		Nerve root L5	Partial sensory deficit			
					Quality	Numb nerve roots	Always		
					Reflexes	Ankle reflex Quadriceps reflex	Normal Reduced	Normal Normal	
			Cauda equina syndrome					N	
			Walking range(m)					<2000	
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0203	NDisc basic	ES/SAF/FAS	Visit 8	Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Ankle extensor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Hip flexor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Knee extensor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Big toe extensor	No deficits (Normal - 5)		No deficits (Normal - 5)
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0203	NDisc basic	ES/SAF/FAS	Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome			N	
				Sciatic stretch test	Negative		Negative	
				Walking range(m)			1000	
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root L4	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Absent	Normal	
				Cauda equina syndrome			N	
				Sciatic stretch test	Negative		Negative	
				Walking range(m)			Unlimited	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0204	NDisc basic ES/SAF		Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Tingle nerve roots	Always		
					Numb nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				1000

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0205	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Intermittent		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome			N	
				Sciatic stretch test		Positive		
				Walking range(m)			ND	
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome			N	
				Sciatic stretch test		Negative	Negative	
				Walking range(m)			Unlimited	
			Visit 3k	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0205	NDisc basic	ES/SAF/FAS	Visit 3k	Motor deficits	Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Absent Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				nd
			Visit 4	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Tingle nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Absent Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0205	NDisc basic	ES/SAF/FAS	Visit 5	Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Hypersensitive nerve roots	Intermittent		
				Reflexes	Ankle reflex Quadriciceps reflex	Absent Normal	Absent Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality	Tingle nerve roots		
					Reflexes	Absent Absent	Absent Absent	
					Cauda equina syndrome			N
					Walking range(m)			Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality	Hypersensitive nerve roots		
				Reflexes	Ankle reflex	Absent	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0205	NDisc basic ES/SAF/FAS		Visit 7	Reflexes	Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
					Quality			
					Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality			
					Tingle nerve roots	Intermittent		
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Absent	Reduced	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0205	NDisc basic	ES/SAF/FAS	Visit 11	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0206	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				not done
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0206	NDisc plus	ES/SAF/FAS	Visit 3a	Reflexes	Ankle reflex Quadriceps reflex	Absent Normal	Absent Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Reflexes	Ankle reflex Quadriceps reflex	Absent Normal	Absent Normal	
				Cauda equina syndrome				N
				Walking range(m)				ND
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
				Quality	Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0206	NDisc plus	ES/SAF/FAS	Visit 5	Reflexes	Ankle reflex	Absent	Absent	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				2000
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Absent	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				>2000
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0206	NDisc plus	ES/SAF/FAS	Visit 7	Sensory deficits	Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				3000
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
					Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0207		ES	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadiceps reflex	Absent	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				UN

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0208	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				>1500
			Visit 3k	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Reflexes	Ankle reflex	Exaggerated	Exaggerated	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0208	NDisc plus	ES/SAF/FAS	Visit 3k	Sciatic stretch test		Positive		
				Walking range(m)				100
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Tingle nerve roots	Intermittent		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0208	NDisc plus	ES/SAF/FAS	Visit 4	Walking range(m)				1000
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				1000
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			d		Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Tingle nerve roots	Intermittent		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0208	NDisc plus	ES/SAF/FAS	Visit 6	Motor deficits	Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				2000
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0208	NDisc plus	ES/SAF/FAS	Visit 7	Quality	Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Unschedule d	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				0500
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General	
02-0208	NDisc plus	ES/SAF/FAS	Visit 8	Sensory deficits	Nerve root L5	None	None		
					Nerve root L4	None	None		
					Nerve root L3	None	None		
					Nerve root L2	None	None		
					Nerve root L1	None	None		
				Quality	Tingle nerve roots	None	None		
					Numb nerve roots	None	None		
					Hypersensitive nerve roots	None	None		
				Reflexes	Ankle reflex	Normal	Normal		
					Quadriceps reflex	Normal	Normal		
				Cauda equina syndrome			N		
				Sciatic stretch test		Negative	Negative		
				Walking range(m)				Unlimited	
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Sensory deficits	Nerve root L5	Partial sensory deficit			
				Quality	Numb nerve roots	Always			
				Reflexes	Ankle reflex	Normal	Normal		
					Quadriceps reflex	Normal	Normal		
				Cauda equina syndrome				N	
				Sciatic stretch test		Negative	Negative		
				Walking range(m)				2000	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0209	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Absent	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Absent	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0209	NDisc plus	ES/SAF/FAS	Visit 4	Motor deficits	Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots Numb nerve roots Hypersensitive nerve roots	None None None	None None None	
				Reflexes	Ankle reflex Quadriiceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots Numb nerve roots Hypersensitive nerve roots	None None None	None None None	
				Reflexes	Ankle reflex Quadriiceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General			
02-0209	NDisc plus	ES/SAF/FAS	Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
				Sensory deficits	Nerve root L5		Partial sensory deficit				
					Numb nerve roots		Always				
					Reflexes	Ankle reflex	Normal	Normal			
				Quadriceps reflex		Normal	Normal				
				Cauda equina syndrome				N			
				Sciatic stretch test				Negative	Negative		
				Walking range(m)				Unlimited			
				Unschedule d	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
			Ankle extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Hip flexor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Knee extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Big toe extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Sensory deficits		Nerve root L5		Partial sensory deficit				
					Numb nerve roots		Always				
					Reflexes	Ankle reflex	Normal	Normal			
			Quadriceps reflex			Normal	Normal				
			Cauda equina syndrome				N				
			Sciatic stretch test				Positive				
			Walking range(m)				Unlimited				
			Visit 7		Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
						Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0209	NDisc plus	ES/SAF/FAS	Visit 7	Motor deficits	Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
			Visit 8	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0209	NDisc plus	ES/SAF/FAS	Visit 8	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Ankle extensor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Hip flexor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Knee extensor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Big toe extensor	No deficits (Normal - 5)		No deficits (Normal - 5)
				Sensory deficits	Nerve root L5		Partial sensory deficit	
					Quality	Numb nerve roots		Always
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0210	ES		Visit 1	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Tingle nerve roots	Always		
				Reflexes	Ankle reflex	Exaggerated	Exaggerated	
					Quadiceps reflex	Exaggerated	Exaggerated	
				Cauda equina syndrome				
Sciatic stretch test	Positive							
Walking range(m)	300							

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0211	NDisc basic ES/SAF		Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0211	NDisc basic ES/SAF		Visit 3a	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0212	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0212	SC	ES/SAF/FAS	Visit 4	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor			
					Ankle extensor			
					Hip flexor			
					Knee extensor			
					Big toe extensor			
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0212	SC	ES/SAF/FAS	Visit 6	Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0212	SC	ES/SAF/FAS	Visit 8	Motor deficits	Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0212	SC	ES/SAF/FAS	Visit 11	Quality	Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0213	NDisc plus	ES/SAF	Baseline (Visit 2a)	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0214	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0214	NDisc plus	ES/SAF/FAS	Visit 3a	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Exaggerated	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Negative
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Exaggerated	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Negative
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0214	NDisc plus	ES/SAF/FAS	Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				1000
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0214	NDisc plus	ES/SAF/FAS	Visit 7	Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0215	ES		Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0216	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	Very few deficits (4)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Numb nerve roots		Always	
					Reflexes	Ankle reflex	Reduced	Absent
				Quadriceps reflex		Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
				Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)
			Ankle extensor			No deficits (Normal - 5)	No deficits (Normal - 5)	
			Hip flexor			No deficits (Normal - 5)	No deficits (Normal - 5)	
			Knee extensor			No deficits (Normal - 5)	No deficits (Normal - 5)	
			Big toe extensor			No deficits (Normal - 5)	No deficits (Normal - 5)	
			Sensory deficits		Nerve root S1		Partial sensory deficit	
					Tingle nerve roots		None	
					Numb nerve roots		None	
					Hypersensitive nerve roots		None	
			Reflexes		Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
			Cauda equina syndrome				N	
			Sciatic stretch test		Negative	Negative		
			Walking range(m)				Unlimited	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0217	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive	Positive	
				Walking range(m)				0000
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0217	SC	ES/SAF/FAS	Visit 4	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
			Visit 5	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Visit 6	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
		ES/SAF/FAS	Visit 7	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
			Visit 8	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0217	SC	ES/SAF/FAS	Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Very few deficits (4)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0217	SC	ES/SAF/FAS	Visit 7	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0217	SC	ES/SAF/FAS	Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0218	NDisc basic	ES/SAF	Baseline (Visit 2a)	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				Y
				Sciatic stretch test			Positive	
				Walking range(m)				1000

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General			
02-0219	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
				Sensory deficits	Nerve root S1	Partial sensory deficit					
				Quality	Numb nerve roots	Always					
				Reflexes	Ankle reflex	Absent	Normal				
					Quadriceps reflex	Absent	Absent				
				Cauda equina syndrome							N
				Sciatic stretch test							Positive
				Walking range(m)							Unlimited
				Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
			Ankle extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Hip flexor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Knee extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Big toe extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Sensory deficits		Nerve root S1	None	None				
					Nerve root S2	None	None				
					Nerve root L5	None	None				
					Nerve root L4	None	None				
					Nerve root L3	None	None				
					Nerve root L2	None	None				
					Nerve root L1	None	None				
			Quality		Tingle nerve roots	None	None				
					Numb nerve roots	None	None				
					Hypersensitive nerve roots	None	None				
			Reflexes		Ankle reflex	Normal	Normal				
					Quadriceps reflex	Normal	Normal				

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0219	NDisc basic	ES/SAF/FAS	Visit 3a	Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex	Normal	Normal
				Quadriceps reflex		Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				Unlimited
				Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)
						Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)
			Hip flexor			No deficits (Normal - 5)	No deficits (Normal - 5)	
			Knee extensor			No deficits (Normal - 5)	No deficits (Normal - 5)	
			Big toe extensor			No deficits (Normal - 5)	No deficits (Normal - 5)	
			Sensory deficits		Nerve root L5	Partial sensory deficit		
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex	Normal	Normal
			Quadriceps reflex			Normal	Normal	
			Cauda equina syndrome				N	
			Sciatic stretch test				Positive	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0219	NDisc basic	ES/SAF/FAS	Visit 5	Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality		Numb nerve roots	
					Reflexes		Ankle reflex Normal	
				Cauda equina syndrome	Quadriciceps reflex		Normal	
					Sciatic stretch test		Negative	
					Walking range(m)		Unlimited	
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		None	
					Nerve root S2		None	
					Nerve root L5		None	
					Nerve root L4		None	
					Nerve root L3		None	
					Nerve root L2		None	
					Nerve root L1		None	
				Quality	Tingle nerve roots		None	
					Numb nerve roots		None	
					Hypersensitive nerve roots		None	
				Reflexes	Ankle reflex		Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0219	NDisc basic ES/SAF/FAS		Visit 7	Reflexes	Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0219	NDisc basic	ES/SAF/FAS	Visit 11	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0220	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Hypersensitive nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0220	SC	ES/SAF/FAS	Visit 4	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Complete sensory deficit		
					Quality			
					Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General			
02-0220	SC	ES/SAF/FAS	Visit 6	Quality	Tingle nerve roots	None	None				
					Numb nerve roots	None	None				
					Hypersensitive nerve roots	None	None				
				Reflexes	Ankle reflex	Normal	Normal				
					Quadriceps reflex	Normal	Normal				
				Cauda equina syndrome					N		
				Sciatic stretch test					Negative	Negative	
				Walking range(m)					Unlimited		
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
				Sensory deficits	Nerve root S1	None	None				
					Nerve root S2	None	None				
					Nerve root L5	None	None				
					Nerve root L4	None	None				
					Nerve root L3	None	None				
					Nerve root L2	None	None				
					Nerve root L1	None	None				
				Quality	Tingle nerve roots	None	None				
					Numb nerve roots	None	None				
					Hypersensitive nerve roots	None	None				
				Reflexes	Ankle reflex	Normal	Normal				
					Quadriceps reflex	Normal	Normal				
				Cauda equina syndrome				N			
				Sciatic stretch test				Negative	Negative		
				Walking range(m)				Unlimited			

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0220	SC	ES/SAF/FAS	Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0220	SC	ES/SAF/FAS	Visit 11	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0221	NDisc plus	ES/SAF	Visit 1	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Tingle nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0221	NDisc plus	ES/SAF	Visit 3a	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0222	NDisc plus	ES/SAF	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriiceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0223	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	Few deficits (3)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Few deficits (3)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Reduced	Reduced	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0223	NDisc basic	ES/SAF/FAS	Visit 3a	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Very few deficits (4)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Very few deficits (4)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0223	NDisc basic	ES/SAF/FAS	Visit 5	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0223	NDisc basic	ES/SAF/FAS	Visit 7	Motor deficits	Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Very few deficits (4)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
					Numb nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0223	NDisc basic	ES/SAF/FAS	Visit 8	Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
02-0224	NDisc plus	ES/SAF	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
04-0401	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				4000
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
04-0401	SC	ES/SAF/FAS	Visit 4	Quality	Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
04-0401	SC	ES/SAF/FAS	Visit 6	Motor deficits	Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome			N	
				Sciatic stretch test		Negative	Negative	
				Walking range(m)			Unlimited	
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
04-0401	SC	ES/SAF/FAS	Visit 7	Quality	Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
04-0401	SC	ES/SAF/FAS	Visit 11	Motor deficits	Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0602	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L4	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Reduced	Normal	
				Cauda equina syndrome				N
				Walking range(m)				>9999
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 3k	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0602	NDisc plus	ES/SAF/FAS	Visit 3k	Motor deficits	Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Reduced	Normal	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0602	NDisc plus	ES/SAF/FAS	Visit 4	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0602	NDisc plus	ES/SAF/FAS	Visit 7	Sensory deficits	Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0604	NDisc basic	ES/SAF	Baseline (Visit 2a)	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				200

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0605	NDisc plus	ES/SAF	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality	Numb nerve roots		
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0606	SC	ES/SAF/FAS	Baseline (Visit 2a)	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0606	SC	ES/SAF/FAS	Visit 4	Sensory deficits	Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Nerve root S2		Partial sensory deficit	
					Nerve root L3		Partial sensory deficit	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				1000
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0606	SC	ES/SAF/FAS	Visit 6	Motor deficits	Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0606	SC	ES/SAF/FAS	Visit 7	Quality	Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex Quadriceps reflex	Absent Normal	Absent Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				5000
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0606	SC	ES/SAF/FAS	Visit 11	Motor deficits	Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General			
06-0607	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
				Sensory deficits	Nerve root S1		Partial sensory deficit				
					Numb nerve roots		Always				
					Reflexes	Ankle reflex	Normal	Normal			
				Quadriceps reflex		Normal	Normal				
				Cauda equina syndrome							N
				Sciatic stretch test							Positive
				Walking range(m)							Unlimited
				Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
			Ankle extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Hip flexor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Knee extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Big toe extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Sensory deficits		Nerve root S1		None	None			
					Nerve root S2		None	None			
					Nerve root L5		None	None			
					Nerve root L4		None	None			
					Nerve root L3		None	None			
					Nerve root L2		None	None			
					Nerve root L1		None	None			
			Quality		Tingle nerve roots		None	None			
					Numb nerve roots		None	None			
					Hypersensitive nerve roots		None	None			
			Reflexes		Ankle reflex		Normal	Normal			
					Quadriceps reflex		Normal	Normal			

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0607	NDisc plus	ES/SAF/FAS	Visit 3a	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				5000
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				5000
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0607	NDisc plus	ES/SAF/FAS	Visit 5	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0607	NDisc plus	ES/SAF/FAS	Visit 6	Reflexes	Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0607	NDisc plus	ES/SAF/FAS	Visit 8	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Exaggerated	Exaggerated	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Unschedule d	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0607	NDisc plus	ES/SAF/FAS	Unscheduled	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0608	SC	ES/SAF	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriiceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0609	NDisc basic ES/SAF		Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Complete sensory deficit	
				Quality	Tingle nerve roots		Always	
					Numb nerve roots		Always	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				2000

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0610	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Tingle nerve roots	Intermittent		
					Numb nerve roots	Intermittent		
				Reflexes	Ankle reflex	Exaggerated	Exaggerated	
					Quadriceps reflex	Exaggerated	Exaggerated	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Exaggerated	Exaggerated	
					Quadriceps reflex	Exaggerated	Exaggerated	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0610	NDisc plus	ES/SAF/FAS	Visit 3a	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General		
06-0610	NDisc plus	ES/SAF/FAS	Visit 5	Sensory deficits	Nerve root S2	None	None			
					Nerve root L5	None	None			
					Nerve root L4	None	None			
					Nerve root L3	None	None			
					Nerve root L2	None	None			
					Nerve root L1	None	None			
				Quality	Tingle nerve roots	None	None			
					Numb nerve roots	None	None			
					Hypersensitive nerve roots	None	None			
				Reflexes	Ankle reflex	Normal	Normal			
					Quadriceps reflex	Normal	Normal			
				Cauda equina syndrome				N		
				Sciatic stretch test				Negative	Negative	
				Walking range(m)				Unlimited		
			Unschedule d	Motor deficits	Ankle flexor	No deficits (Normal - 5)		No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	Partial sensory deficit		Partial sensory deficit		
					Nerve root L5					
				Quality	Numb nerve roots	Always				
				Reflexes	Ankle reflex	Normal	Normal			
					Quadriceps reflex	Normal	Normal			
				Cauda equina syndrome				N		
				Sciatic stretch test				Positive		
				Walking range(m)				20		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0610	NDisc plus	ES/SAF/FAS	Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Nerve root L5	Partial sensory deficit		
					Nerve root L4	Partial sensory deficit		
					Nerve root L3	Partial sensory deficit		
					Nerve root L2	Partial sensory deficit		
					Nerve root L1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Reduced	Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0611	ES		Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				0100

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0612	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Absent	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				1000
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0612	NDisc plus	ES/SAF/FAS	Visit 3a	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Absent	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Ankle extensor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Hip flexor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Knee extensor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Big toe extensor	No deficits (Normal - 5)		No deficits (Normal - 5)
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Reduced	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0612	NDisc plus	ES/SAF/FAS	Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Reduced	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				4000
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0612	NDisc plus	ES/SAF/FAS	Visit 6	Quality	Tingle nerve roots Numb nerve roots Hypersensitive nerve roots	None None None	None None None	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Reduced	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				5000
		Unschedule d		Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1 Nerve root S2 Nerve root L5 Nerve root L4 Nerve root L3 Nerve root L2 Nerve root L1	None None None None None None None	None None None None None None None	
				Quality	Tingle nerve roots Numb nerve roots Hypersensitive nerve roots	None None None	None None None	
				Reflexes	Ankle reflex Quadriceps reflex	Reduced Reduced	Reduced Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0612	NDisc plus	ES/SAF/FAS	Unscheduled	Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Reduced	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0612	NDisc plus	ES/SAF/FAS	Visit 8	Sensory deficits	Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Reduced	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
		Unscheduled	Motor deficits	Ankle flexor		No deficits (Normal - 5)	No deficits (Normal - 5)	
				Ankle extensor		No deficits (Normal - 5)	No deficits (Normal - 5)	
				Hip flexor		No deficits (Normal - 5)	No deficits (Normal - 5)	
				Knee extensor		No deficits (Normal - 5)	No deficits (Normal - 5)	
				Big toe extensor		Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Absent	Normal	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0612	NDisc plus	ES/SAF/FAS	Unscheduled	Walking range(m)				3000
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Absent	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				5000

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0613	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L4		Partial sensory deficit	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Reduced	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0613	SC	ES/SAF/FAS	Visit 4	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0613	SC	ES/SAF/FAS	Visit 6	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0613	SC	ES/SAF/FAS	Visit 7	Reflexes	Quadriceps reflex	Normal	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0613	SC	ES/SAF/FAS	Visit 11	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0614	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	Very few deficits (4)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Nerve root L5		Partial sensory deficit	
					Nerve root L4		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Tingle nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0614	NDisc plus	ES/SAF/FAS	Visit 4	Motor deficits	Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Absent	Absent	
				Cauda equina syndrome				N
				Walking range(m)				4000
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0614	NDisc plus	ES/SAF/FAS	Visit 5	Walking range(m)				1500
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				1500
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots		Always	
					Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0614	NDisc plus	ES/SAF/FAS	Unscheduled	Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Very few deficits (4)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				3000
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			d		Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Numb nerve roots		Always	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0614	NDisc plus	ES/SAF/FAS	Unscheduled	Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Reduced	
					Cauda equina syndrome			N
					Sciatic stretch test		Positive	
					Walking range(m)			Unlimited
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Sensory deficits		Partial sensory deficit	
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex	Absent	
						Quadriceps reflex	Reduced	
					Cauda equina syndrome			N
					Sciatic stretch test		Positive	
					Walking range(m)			Unlimited
		Visit 7		Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0614	NDisc plus	ES/SAF/FAS	Visit 7	Sensory deficits	Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
			Visit 8	Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				2000
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Visit 11	Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Numb nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				3000
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0614	NDisc plus	ES/SAF/FAS	Visit 11	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0615	NDisc basic ES/SAF		Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	Very few deficits (4)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Very few deficits (4)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				2000

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0616		ES	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	Very few deficits (4)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L4		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadiceps reflex	Normal	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0617	NDisc plus	ES/SAF	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Few deficits (3)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				50
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Many deficits (2)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				300

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0618		ES	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex Quadiceps reflex	Reduced Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0619	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0619	NDisc basic	ES/SAF/FAS	Visit 3a	Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriiceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0619	NDisc basic	ES/SAF/FAS	Visit 5	Sensory deficits	Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Reduced	
				Cauda equina syndrome				N
			Visit 6	Sciatic stretch test		Negative	Negative	Unlimited
				Walking range(m)				
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Visit 6	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
			Visit 6	Reflexes	Ankle reflex	Absent	Absent	
					Quadriiceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0619	NDisc basic	ES/SAF/FAS	Visit 6	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0619	NDisc basic	ES/SAF/FAS	Visit 8	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				2000

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0620	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0620	SC	ES/SAF/FAS	Visit 4	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
			Visit 5	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Visit 6	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
			Visit 7	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
			Visit 8	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0620	SC	ES/SAF/FAS	Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0620	SC	ES/SAF/FAS	Visit 7	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
06-0620	SC	ES/SAF/FAS	Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0701	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots		Intermittent	
					Numb nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Negative
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0701	NDisc plus	ES/SAF/FAS	Visit 4	Motor deficits	Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0701	NDisc plus	ES/SAF/FAS	Visit 5	Quality	Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
			Visit 6	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0701	NDisc plus	ES/SAF/FAS	Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0701	NDisc plus	ES/SAF/FAS	Visit 8	Quality	Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0702	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				3
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots Numb nerve roots		Intermittent Intermittent	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0702	SC	ES/SAF/FAS	Visit 5	Motor deficits	Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0702	SC	ES/SAF/FAS	Visit 6	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Ankle extensor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Hip flexor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Knee extensor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Big toe extensor	No deficits (Normal - 5)		No deficits (Normal - 5)
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality		Intermittent	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0703	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	Very few deficits (4)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Few deficits (3)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots		Intermittent	
					Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Few deficits (3)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots		Intermittent	
					Numb nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General			
07-0703	NDisc plus	ES/SAF/FAS	Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Big toe extensor	No deficits (Normal - 5)	Very few deficits (4)				
				Sensory deficits	Nerve root L5		Partial sensory deficit				
					Numb nerve roots		Intermittent				
					Reflexes	Ankle reflex	Normal	Normal			
				Quadriceps reflex		Normal	Normal				
				Cauda equina syndrome							N
				Sciatic stretch test	Negative		Negative				
				Walking range(m)							Unlimited
				Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
						Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
						Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
			Knee extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Big toe extensor			No deficits (Normal - 5)	Very few deficits (4)				
			Sensory deficits		Nerve root L5		Partial sensory deficit				
					Tingle nerve roots		Intermittent				
					Reflexes	Ankle reflex	Normal	Normal			
			Quadriceps reflex			Normal	Normal				
			Cauda equina syndrome								N
			Sciatic stretch test		Negative		Negative				
			Walking range(m)								Unlimited
			Visit 6		Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
						Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
						Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0703	NDisc plus	ES/SAF/FAS	Visit 6	Motor deficits	Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) Very few deficits (4)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots Numb nerve roots Hypersensitive nerve roots	None None None	None None None	
				Reflexes	Ankle reflex Quadriiceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) Very few deficits (4)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots Numb nerve roots Hypersensitive nerve roots	None None None	None None None	
				Reflexes	Ankle reflex Quadriiceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0703	NDisc plus	ES/SAF/FAS	Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0703	NDisc plus	ES/SAF/FAS	Visit 11	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General			
07-0704	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)				
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Big toe extensor	Few deficits (3)	No deficits (Normal - 5)				
				Sensory deficits	Nerve root L5	Partial sensory deficit					
				Quality	Numb nerve roots	Always					
				Reflexes	Ankle reflex	Normal	Normal				
					Quadriceps reflex	Normal	Normal				
				Cauda equina syndrome							N
				Sciatic stretch test							Positive
				Walking range(m)							4000
				Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
			Ankle extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Hip flexor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Knee extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Big toe extensor			No deficits (Normal - 5)	No deficits (Normal - 5)				
			Sensory deficits		Nerve root S1	None	None				
					Nerve root S2	None	None				
					Nerve root L5	None	None				
					Nerve root L4	None	None				
					Nerve root L3	None	None				
					Nerve root L2	None	None				
					Nerve root L1	None	None				
			Quality		Tingle nerve roots	None	None				
					Numb nerve roots	None	None				
					Hypersensitive nerve roots	None	None				
			Reflexes		Ankle reflex	Normal	Normal				
					Quadriceps reflex	Normal	Normal				

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0704	NDisc basic	ES/SAF/FAS	Visit 3a	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0704	NDisc basic	ES/SAF/FAS	Visit 5	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0704	NDisc basic ES/SAF/FAS		Visit 6	Reflexes	Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0704	NDisc basic	ES/SAF/FAS	Visit 8	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	Unlimited
				Walking range(m)				
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0704	NDisc basic	ES/SAF/FAS	Visit 11	Reflexes	Ankle reflex	Normal	Normal	
					Quadiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0705		ES	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	Very few deficits (4)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots		Always	
					Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				0050

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0706	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	Very few deficits (4)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L4		Partial sensory deficit	
				Quality	Numb nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Reduced	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0706	SC	ES/SAF/FAS	Visit 4	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				1000

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
07-0707		ES	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Few deficits (3)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Nerve root L5	Partial sensory deficit		
				Quality	Tingle nerve roots	Intermittent		
					Numb nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				0050

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0801	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	Few deficits (3)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Knee extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Big toe extensor	Few deficits (3)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				50
			Visit 4	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				300
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0801	SC	ES/SAF/FAS	Visit 5	Motor deficits	Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				1000
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0801	SC	ES/SAF/FAS	Visit 6	Quality	Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				500

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0802	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L4		Partial sensory deficit	
					Nerve root L3		Partial sensory deficit	
				Quality	Tingle nerve roots		Always	
					Numb nerve roots		Always	
				Reflexes	Ankle reflex	Reduced	Absent	
					Quadriciceps reflex	Reduced	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				1500
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Reduced	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0802	NDisc plus	ES/SAF/FAS	Visit 3a	Sciatic stretch test		Negative	Negative	
				Walking range(m)				3000
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				7000
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General			
08-0802	NDisc plus	ES/SAF/FAS	Visit 5	Sensory deficits	Nerve root L4	None	None				
					Nerve root L3	None	None				
					Nerve root L2	None	None				
					Nerve root L1	None	None				
				Quality	Tingle nerve roots	None	None				
					Numb nerve roots	None	None				
					Hypersensitive nerve roots	None	None				
				Reflexes	Ankle reflex	Normal	Normal				
					Quadriceps reflex	Normal	Normal				
				Cauda equina syndrome				N			
				Sciatic stretch test		Negative	Negative				
				Walking range(m)				Unlimited			
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
				Sensory deficits	Nerve root S1	None	None				
					Nerve root S2	None	None				
					Nerve root L5	None	None				
					Nerve root L4	None	None				
					Nerve root L3	None	None				
					Nerve root L2	None	None				
					Nerve root L1	None	None				
				Quality	Tingle nerve roots	None	None				
					Numb nerve roots	None	None				
					Hypersensitive nerve roots	None	None				
				Reflexes	Ankle reflex	Normal	Normal				
					Quadriceps reflex	Normal	Normal				

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0802	NDisc plus	ES/SAF/FAS	Visit 6	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0802	NDisc plus	ES/SAF/FAS	Visit 8	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0802	NDisc plus	ES/SAF/FAS	Visit 11	Reflexes	Quadriceps reflex	Normal	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0803	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	Few deficits (3)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Many deficits (2)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive	Positive	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0803	NDisc basic	ES/SAF/FAS	Visit 4	Motor deficits	Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Intermittent		
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0804	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L4	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0804	NDisc plus	ES/SAF/FAS	Visit 3a	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriiceps reflex	Reduced	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0804	NDisc plus	ES/SAF/FAS	Visit 5	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0804	NDisc plus	ES/SAF/FAS	Visit 6	Reflexes	Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0804	NDisc plus	ES/SAF/FAS	Visit 8	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	Unlimited
				Walking range(m)				
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0804	NDisc plus	ES/SAF/FAS	Visit 11	Reflexes	Ankle reflex Quadriceps reflex	Absent Reduced	Reduced Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0805	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L3	Partial sensory deficit	Complete sensory deficit	
				Quality	Numb nerve roots	Always	Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Baseline (Visit 2a)	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L3	Partial sensory deficit	Complete sensory deficit	
				Quality	Numb nerve roots	Always	Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0805	NDisc basic	ES/SAF/FAS	Visit 3a	Motor deficits	Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0805	NDisc basic ES/SAF/FAS		Visit 4	Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				1000
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0805	NDisc basic	ES/SAF/FAS	Visit 6	Motor deficits	Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
		Unscheduled		Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L3		Partial sensory deficit	
				Quality	Numb nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0805	NDisc basic	ES/SAF/FAS	Unscheduled	Walking range(m)				500
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0805	NDisc basic	ES/SAF/FAS	Visit 8	Sensory deficits	Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0805	NDisc basic	ES/SAF/FAS	Visit 11	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0806	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L3		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Reduced	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0806	NDisc plus	ES/SAF/FAS	Visit 3a	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				5000
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0806	NDisc plus	ES/SAF/FAS	Visit 5	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0806	NDisc plus	ES/SAF/FAS	Visit 6	Reflexes	Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0806	NDisc plus	ES/SAF/FAS	Visit 8	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0806	NDisc plus	ES/SAF/FAS	Visit 11	Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0807	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				200
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0807	NDisc plus	ES/SAF/FAS	Visit 3a	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Exaggerated	Exaggerated	
					Quadriceps reflex	Exaggerated	Exaggerated	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				1000
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				1000

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0807	NDisc plus	ES/SAF/FAS	Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive	Positive	
				Walking range(m)				1000
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0807	NDisc plus	ES/SAF/FAS	Visit 5	Sensory deficits	Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0807	NDisc plus	ES/SAF/FAS	Visit 6	Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General			
08-0807	NDisc plus	ES/SAF/FAS	Visit 8	Sensory deficits	Nerve root L2	None	None				
					Nerve root L1	None	None				
				Quality	Tingle nerve roots	None	None				
					Numb nerve roots	None	None				
					Hypersensitive nerve roots	None	None				
				Reflexes	Ankle reflex	Normal	Normal				
					Quadiceps reflex	Normal	Normal				
				Cauda equina syndrome							N
				Sciatic stretch test					Negative	Negative	
				Walking range(m)							Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0808	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Knee extensor	No deficits (Normal - 5)	Very few deficits (4)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				300
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Knee extensor	No deficits (Normal - 5)	Very few deficits (4)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General	
08-0808	SC	ES/SAF/FAS	Visit 4	Quality	Tingle nerve roots	None	None		
					Numb nerve roots	None	None		
					Hypersensitive nerve roots	None	None		
				Reflexes	Ankle reflex	Normal	Normal		
					Quadriceps reflex	Normal	Absent		
				Cauda equina syndrome					N
				Sciatic stretch test		Negative	Negative		
				Walking range(m)					Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)		No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)		No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)		No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)		Very few deficits (4)	
					Big toe extensor	No deficits (Normal - 5)		No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None		
					Nerve root S2	None	None		
					Nerve root L5	None	None		
					Nerve root L4	None	None		
					Nerve root L3	None	None		
					Nerve root L2	None	None		
					Nerve root L1	None	None		
				Quality	Tingle nerve roots	None	None		
					Numb nerve roots	None	None		
					Hypersensitive nerve roots	None	None		
				Reflexes	Ankle reflex	Normal	Normal		
					Quadriceps reflex	Normal	Absent		
				Cauda equina syndrome				N	
				Sciatic stretch test		Negative	Negative		
				Walking range(m)				Unlimited	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0808	SC	ES/SAF/FAS	Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
08-0808	SC	ES/SAF/FAS	Visit 7	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Ankle extensor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Hip flexor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Knee extensor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Big toe extensor	No deficits (Normal - 5)		No deficits (Normal - 5)
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0901	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Tingle nerve roots		Intermittent	
					Reflexes	Ankle reflex	Normal	Normal
				Quadriceps reflex		Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
				Baseline (Visit 2a)	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)
			Ankle extensor			No deficits (Normal - 5)	No deficits (Normal - 5)	
			Hip flexor			No deficits (Normal - 5)	No deficits (Normal - 5)	
			Knee extensor			No deficits (Normal - 5)	No deficits (Normal - 5)	
			Big toe extensor			No deficits (Normal - 5)	No deficits (Normal - 5)	
			Sensory deficits		Nerve root S1		Partial sensory deficit	
					Tingle nerve roots		Intermittent	
					Reflexes	Ankle reflex	Normal	Normal
			Quadriceps reflex			Normal	Normal	
			Cauda equina syndrome				N	
			Sciatic stretch test		Negative	Negative		
			Walking range(m)				Unlimited	
			Visit 4		Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)
				Ankle extensor		No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0901	SC	ES/SAF/FAS	Visit 4	Motor deficits	Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Hypersensitive nerve roots		Intermittent	
				Cauda equina syndrome				N
				Sciatic stretch test				

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0901	SC	ES/SAF/FAS	Visit 5	Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0901	SC	ES/SAF/FAS	Visit 7	Sensory deficits	Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
			Visit 8	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0901	SC	ES/SAF/FAS	Visit 8	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0902		ES	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits				
					Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots		Intermittent	
				Reflexes	Ankle reflex	Reduced	Absent	
					Quadiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				1000

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0903	NDisc plus	ES/SAF	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	Very few deficits (4)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Many deficits (2)	
				Sensory deficits	Nerve root L5		Complete sensory deficit	
					Nerve root L4		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				500
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	Very few deficits (4)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Few deficits (3)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0904	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Very few deficits (4)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Complete sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Absent	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				30
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Few deficits (3)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Tingle nerve roots	Always		
					Numb nerve roots	Always		
					Hypersensitive nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				1500

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0904	NDisc basic	ES/SAF/FAS	Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Few deficits (3)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Tingle nerve roots	Always		
					Numb nerve roots	Always		
					Hypersensitive nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Few deficits (3)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Tingle nerve roots	Always		
					Numb nerve roots	Always		
					Hypersensitive nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0904	NDisc basic	ES/SAF/FAS	Visit 5	Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Tingle nerve roots	Always		
					Numb nerve roots	Always		
					Hypersensitive nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Tingle nerve roots	Always		
					Numb nerve roots	Always		
					Hypersensitive nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0904	NDisc basic	ES/SAF/FAS	Visit 7	Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Tingle nerve roots	Always		
					Numb nerve roots	Always		
					Hypersensitive nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Tingle nerve roots	Always		
					Numb nerve roots	Always		
					Hypersensitive nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriceps reflex	Absent	Absent	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0904	NDisc basic	ES/SAF/FAS	Visit 11	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0905	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				0200
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0905	NDisc plus	ES/SAF/FAS	Visit 3a	Quality	Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
			Visit 4	Sciatic stretch test		Negative	Negative	
				Walking range(m)				1500
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0905	NDisc plus	ES/SAF/FAS	Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0905	NDisc plus	ES/SAF/FAS	Visit 6	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0905	NDisc plus	ES/SAF/FAS	Visit 8	Motor deficits	Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	Very few deficits (4)	
					Hip flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Knee extensor	No deficits (Normal - 5)	Very few deficits (4)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0905	NDisc plus	ES/SAF/FAS	Unscheduled	Quality	Hypersensitive nerve roots		Always	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				0100
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Hypersensitive nerve roots		Always	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				1000
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0905	NDisc plus	ES/SAF/FAS	Visit 11	Motor deficits	Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0906		ES	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	Few deficits (3)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				1000

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0907	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				400
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0907	SC	ES/SAF/FAS	Visit 4	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				2000
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0907	SC	ES/SAF/FAS	Visit 6	Motor deficits	Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General		
09-0907	SC	ES/SAF/FAS	Visit 7	Quality	Tingle nerve roots	None	None			
					Numb nerve roots	None	None			
					Hypersensitive nerve roots	None	None			
				Reflexes	Ankle reflex	Absent	Normal			
					Quadriceps reflex	Normal	Normal			
				Cauda equina syndrome					N	
				Sciatic stretch test					Negative	Negative
				Walking range(m)					Unlimited	
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
				Sensory deficits	Nerve root S1	None	None			
					Nerve root S2	None	None			
					Nerve root L5	None	None			
					Nerve root L4	None	None			
					Nerve root L3	None	None			
					Nerve root L2	None	None			
					Nerve root L1	None	None			
				Quality	Tingle nerve roots	None	None			
					Numb nerve roots	None	None			
					Hypersensitive nerve roots	None	None			
				Reflexes	Ankle reflex	Normal	Normal			
					Quadriceps reflex	Normal	Normal			
				Cauda equina syndrome				N		
				Sciatic stretch test				Negative	Negative	
				Walking range(m)				Unlimited		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0907	SC	ES/SAF/FAS	Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0908	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Few deficits (3)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				100
			Visit 3a	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	Few deficits (3)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0908	NDisc basic ES/SAF/FAS		Visit 4	Motor deficits	Knee extensor Big toe extensor	No deficits (Normal - 5) Very few deficits (4)	No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) Very few deficits (4)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) Very few deficits (4)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0908	NDisc basic	ES/SAF/FAS	Visit 6	Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1 Nerve root S2 Nerve root L5 Nerve root L4 Nerve root L3	None None None None None	None None None None None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0908	NDisc basic	ES/SAF/FAS	Visit 8	Sensory deficits	Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0908	NDisc basic	ES/SAF/FAS	Visit 11	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0909	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Reduced	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				0010
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0909	NDisc plus	ES/SAF/FAS	Visit 3a	Quality	Tingle nerve roots Numb nerve roots Hypersensitive nerve roots	None None None	None None None	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
		Unscheduled	Motor deficits		Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1 Nerve root S2 Nerve root L5 Nerve root L4 Nerve root L3 Nerve root L2 Nerve root L1	None None None None None None None	None None None None None None None	
				Quality	Tingle nerve roots Numb nerve roots Hypersensitive nerve roots	None None None	None None None	
				Reflexes	Ankle reflex Quadriceps reflex	Absent Normal	Normal Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0909	NDisc plus	ES/SAF/FAS	Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0909	NDisc plus	ES/SAF/FAS	Visit 5	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0909	NDisc plus	ES/SAF/FAS	Visit 7	Motor deficits	Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General				
09-0909	NDisc plus	ES/SAF/FAS	Visit 8	Quality	Tingle nerve roots	None	None					
					Numb nerve roots	None	None					
					Hypersensitive nerve roots	None	None					
				Reflexes	Ankle reflex	Normal	Normal					
					Quadriceps reflex	Normal	Normal					
				Cauda equina syndrome					N			
				Sciatic stretch test					Negative	Negative		
				Walking range(m)					Unlimited			
				Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)		No deficits (Normal - 5)			
			Ankle extensor			No deficits (Normal - 5)	No deficits (Normal - 5)					
			Hip flexor			No deficits (Normal - 5)	No deficits (Normal - 5)					
			Knee extensor			No deficits (Normal - 5)	No deficits (Normal - 5)					
			Big toe extensor			No deficits (Normal - 5)	No deficits (Normal - 5)					
			Sensory deficits		Nerve root S1	None	None					
					Nerve root S2	None	None					
					Nerve root L5	None	None					
					Nerve root L4	None	None					
					Nerve root L3	None	None					
					Nerve root L2	None	None					
					Nerve root L1	None	None					
			Quality		Tingle nerve roots	None	None					
					Numb nerve roots	None	None					
					Hypersensitive nerve roots	None	None					
			Reflexes		Ankle reflex	Normal	Normal					
					Quadriceps reflex	Normal	Normal					
			Cauda equina syndrome				N					
			Sciatic stretch test				Negative	Negative				
			Walking range(m)				Unlimited					

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General				
09-0910	NDisc plus	ES/SAF	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)					
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)					
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)					
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)					
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)					
				Sensory deficits	Nerve root S1	Partial sensory deficit						
				Quality	Tingle nerve roots	Intermittent						
				Reflexes	Ankle reflex	Normal	Normal					
					Quadriceps reflex	Normal	Normal					
				Cauda equina syndrome								N
				Sciatic stretch test						Positive		
				Walking range(m)								0

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0911	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				2500
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General	
09-0911	NDisc plus	ES/SAF/FAS	Visit 3a	Cauda equina syndrome				N	
				Sciatic stretch test				Positive	
				Walking range(m)				1000	
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Sensory deficits	Nerve root S1		Partial sensory deficit		
					Quality		Numb nerve roots		Always
					Reflexes		Ankle reflex	Normal	Absent
						Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N	
				Sciatic stretch test				Positive	
				Walking range(m)				4000	
				Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
			Ankle extensor			No deficits (Normal - 5)	No deficits (Normal - 5)		
			Hip flexor			No deficits (Normal - 5)	No deficits (Normal - 5)		
			Knee extensor			No deficits (Normal - 5)	No deficits (Normal - 5)		
			Big toe extensor			No deficits (Normal - 5)	No deficits (Normal - 5)		
			Sensory deficits		Nerve root S1		Partial sensory deficit		
					Quality		Numb nerve roots		Always
					Reflexes		Ankle reflex	Normal	Absent
					Quadriceps reflex	Normal	Normal		
			Cauda equina syndrome				N		
			Sciatic stretch test				Negative		
							Negative		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0911	NDisc plus	ES/SAF/FAS	Visit 5	Walking range(m)				4000
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				4000
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0911	NDisc plus	ES/SAF/FAS	Visit 8	Motor deficits	Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex Quadriceps reflex	Reduced Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Reduced Normal	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0911	NDisc plus	ES/SAF/FAS	Visit 11	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0912	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	Few deficits (3)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				0500
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0912	NDisc plus	ES/SAF/FAS	Visit 3a	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0912	NDisc plus	ES/SAF/FAS	Visit 5	Sensory deficits	Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0912	NDisc plus	ES/SAF/FAS	Visit 6	Reflexes	Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0912	NDisc plus	ES/SAF/FAS	Visit 8	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0912	NDisc plus	ES/SAF/FAS	Visit 11	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0913	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	Very few deficits (4)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Very few deficits (4)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Absent	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0913	NDisc basic	ES/SAF/FAS	Visit 4	Motor deficits	Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots Numb nerve roots Hypersensitive nerve roots		Always Always Always	
				Reflexes	Ankle reflex Quadriiceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots Numb nerve roots Hypersensitive nerve roots		Always Always Always	
				Reflexes	Ankle reflex Quadriiceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0913	NDisc basic	ES/SAF/FAS	Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0913	NDisc basic	ES/SAF/FAS	Unscheduled	Sensory deficits	Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0913	NDisc basic	ES/SAF/FAS	Visit 7	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0913	NDisc basic	ES/SAF/FAS	Visit 11	Sensory deficits	Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0914	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Tingle nerve roots	Intermittent		
					Numb nerve roots	Intermittent		
					Hypersensitive nerve roots	Intermittent		
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				500
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0914	SC	ES/SAF/FAS	Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0914	SC	ES/SAF/FAS	Visit 6	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0914	SC	ES/SAF/FAS	Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0914	SC	ES/SAF/FAS	Visit 11	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0915	NDisc basic ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
			Sensory deficits	Nerve root S1	None	None		
				Nerve root S2	None	None		
				Nerve root L5	None	None		
				Nerve root L4	None	None		
				Nerve root L3	None	None		
				Nerve root L2	None	None		
				Nerve root L1	None	None		
			Quality	Tingle nerve roots	None	None		
				Numb nerve roots	None	None		
				Hypersensitive nerve roots	None	None		
			Reflexes	Ankle reflex	Reduced	Reduced		
				Quadriceps reflex	Reduced	Reduced		
			Cauda equina syndrome					N
			Sciatic stretch test			Positive		
			Walking range(m)					Unlimited
		Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
			Sensory deficits	Nerve root S1	None	None		
				Nerve root S2	None	None		
				Nerve root L5	None	None		
				Nerve root L4	None	None		
				Nerve root L3	None	None		
				Nerve root L2	None	None		
				Nerve root L1	None	None		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0915	NDisc basic ES/SAF/FAS	Visit 3a	Quality		Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General		
09-0915	NDisc basic ES/SAF/FAS		Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)			
				Sensory deficits	Nerve root S1	None	None			
					Nerve root S2	None	None			
					Nerve root L5	None	None			
					Nerve root L4	None	None			
					Nerve root L3	None	None			
					Nerve root L2	None	None			
					Nerve root L1	None	None			
				Quality	Tingle nerve roots	None	None			
					Numb nerve roots	None	None			
					Hypersensitive nerve roots	None	None			
				Reflexes	Ankle reflex	Reduced	Reduced			
			Quadriceps reflex		Reduced	Reduced				
			Cauda equina syndrome				N			
			Sciatic stretch test		Negative	Negative				
			Walking range(m)				Unlimited			
			Visit 6			Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
							Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
							Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
							Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
							Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
						Sensory deficits	Nerve root S1	None	None	
							Nerve root S2	None	None	
							Nerve root L5	None	None	
							Nerve root L4	None	None	
							Nerve root L3	None	None	
							Nerve root L2	None	None	
							Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0915	NDisc basic	ES/SAF/FAS	Visit 6	Quality	Tingle nerve roots Numb nerve roots Hypersensitive nerve roots	None None None	None None None	
				Reflexes	Ankle reflex Quadriceps reflex	Reduced Reduced	Reduced Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
		Unscheduled		Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1 Nerve root S2 Nerve root L5 Nerve root L4 Nerve root L3 Nerve root L2 Nerve root L1	None None None None None None None	None None None None None None None	
				Quality	Tingle nerve roots Numb nerve roots Hypersensitive nerve roots	None None None	None None None	
				Reflexes	Ankle reflex Quadriceps reflex	Reduced Reduced	Reduced Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0915	NDisc basic	ES/SAF/FAS	Unscheduled	Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0915	NDisc basic	ES/SAF/FAS	Visit 8	Sensory deficits	Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Ankle extensor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Hip flexor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Knee extensor	No deficits (Normal - 5)		No deficits (Normal - 5)
					Big toe extensor	No deficits (Normal - 5)		No deficits (Normal - 5)
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Absent	Absent	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0915	NDisc basic	ES/SAF/FAS	Unscheduled	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriciceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0916	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Absent	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				0100
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0916	SC	ES/SAF/FAS	Visit 4	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Reduced	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				300
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				300

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0916	SC	ES/SAF/FAS	Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				2000
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0916	SC	ES/SAF/FAS	Visit 7	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				5000
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
09-0916	SC	ES/SAF/FAS	Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
10-1001		ES	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	Few deficits (3)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1101	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1101	NDisc plus	ES/SAF/FAS	Visit 4	Motor deficits	Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1101	NDisc plus	ES/SAF/FAS	Visit 6	Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1101	NDisc plus	ES/SAF/FAS	Visit 8	Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
				Unscheduled	Motor deficits	Ankle flexor	Many deficits (2)	No deficits (Normal - 5)
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Intermittent		
					Hypersensitive nerve roots	Intermittent		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				Unlimited
				Unscheduled	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1101	NDisc plus	ES/SAF/FAS	Unscheduled	Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	
					Cauda equina syndrome			N
					Sciatic stretch test	Positive		
					Walking range(m)			Unlimited
				Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Sensory deficits	Nerve root S1	Partial sensory deficit	
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex	Reduced	Normal
						Quadriceps reflex	Normal	Normal
					Cauda equina syndrome			N
					Sciatic stretch test	Positive		
					Walking range(m)			Unlimited
		Visit 11		Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex	Reduced	Normal

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1101	NDisc plus	ES/SAF/FAS	Visit 11	Reflexes	Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1102	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Complete sensory deficit		
				Quality	Tingle nerve roots	Intermittent		
					Numb nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				0005
			Baseline (Visit 2a)	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Complete sensory deficit		
				Quality	Tingle nerve roots	Intermittent		
					Numb nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				0005

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1102	NDisc basic	ES/SAF/FAS	Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				Y
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1102	NDisc basic	ES/SAF/FAS	Visit 4	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1102	NDisc basic ES/SAF/FAS	Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
			Sensory deficits	Nerve root S1	None	None		
				Nerve root S2	None	None		
				Nerve root L5	None	None		
				Nerve root L4	None	None		
				Nerve root L3	None	None		
				Nerve root L2	None	None		
				Nerve root L1	None	None		
			Quality	Tingle nerve roots	None	None		
				Numb nerve roots	None	None		
				Hypersensitive nerve roots	None	None		
			Reflexes	Ankle reflex	Normal	Normal		
				Quadriciceps reflex	Normal	Normal		
			Cauda equina syndrome					N
			Sciatic stretch test		Negative	Negative		
			Walking range(m)					Unlimited
		Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
				Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)		
			Sensory deficits	Nerve root S1	None	None		
				Nerve root S2	None	None		
				Nerve root L5	None	None		
				Nerve root L4	None	None		
				Nerve root L3	None	None		
				Nerve root L2	None	None		
				Nerve root L1	None	None		

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1102	NDisc basic	ES/SAF/FAS	Visit 7	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1102	NDisc basic	ES/SAF/FAS	Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General			
11-1103	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)				
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
				Sensory deficits	Nerve root S1	Partial sensory deficit					
					Quality	Tingle nerve roots					
					Reflexes	Ankle reflex Quadriiceps reflex	Absent Normal		Normal Normal		
				Cauda equina syndrome						N	
				Sciatic stretch test						Positive	
				Walking range(m)						0050	
			Baseline (Visit 2a)	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)				
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)				
				Sensory deficits	Nerve root S1	Partial sensory deficit					
					Quality	Tingle nerve roots					
					Reflexes	Ankle reflex Quadriiceps reflex	Absent Normal		Normal Normal		
				Cauda equina syndrome						N	
				Sciatic stretch test						Positive	
				Walking range(m)						0050	
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)				
					Ankle extensor	Very few deficits (4)	No deficits (Normal - 5)				

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1103	SC	ES/SAF/FAS	Visit 4	Motor deficits	Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				2500
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Tingle nerve roots	Always		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1103	SC	ES/SAF/FAS	Visit 5	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality	Numb nerve roots		
					Reflexes	Ankle reflex	Absent	Normal
						Quadriceps reflex	Normal	Normal
				Cauda equina syndrome				N
			Visit 7	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality	Numb nerve roots		
					Reflexes	Ankle reflex	Absent	Normal
						Quadriceps reflex	Normal	Normal
				Cauda equina syndrome				N
			Visit 8	Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1103	SC	ES/SAF/FAS	Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Nerve root S2		Partial sensory deficit	
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor	Few deficits (3)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Tingle nerve roots	Intermittent		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				500

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1103	SC	ES/SAF/FAS	Unscheduled	Motor deficits	Ankle flexor	Few deficits (3)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality	Tingle nerve roots		
					Reflexes	Absent	Normal	
				Cauda equina syndrome	Quadriceps reflex	Normal	Normal	
					Sciatic stretch test	Positive		N
					Walking range(m)			Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
				Quality	Nerve root L2	None	None	
					Nerve root L1	None	None	
					Tingle nerve roots	None	None	
				Reflexes	Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
					Ankle reflex	Reduced	Normal	
					Quadriceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1103	SC	ES/SAF/FAS	Visit 11	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				2500

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1104	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	Few deficits (3)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality	Numb nerve roots		
					Reflexes	Ankle reflex Quadriiceps reflex	Absent Normal	Normal Normal
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Baseline (Visit 2a)	Motor deficits	Ankle flexor	Few deficits (3)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality	Numb nerve roots		
					Reflexes	Ankle reflex Quadriiceps reflex	Absent Normal	Normal Normal
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	Few deficits (3)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1104	NDisc plus	ES/SAF/FAS	Visit 3a	Motor deficits	Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
			Visit 4	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
				Motor deficits	Ankle flexor	Few deficits (3)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex	Absent	Normal	
					Quadriceps reflex	Normal	Normal	
			Visit 5	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
				Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1104	NDisc plus	ES/SAF/FAS	Visit 5	Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	Very few deficits (4) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Reduced Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	Very few deficits (4) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Numb nerve roots	Always		
				Reflexes	Ankle reflex Quadriceps reflex	Reduced Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1104	NDisc plus	ES/SAF/FAS	Visit 7	Reflexes	Ankle reflex Quadriceps reflex	Reduced Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex Quadriceps reflex	Reduced Normal	Normal Normal
			Visit 11	Motor deficits	Cauda equina syndrome			N
					Sciatic stretch test	Negative	Negative	
					Walking range(m)			Unlimited
					Ankle flexor	Very few deficits (4)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex Quadriceps reflex	Reduced Normal	Normal Normal

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
11-1104	NDisc plus	ES/SAF/FAS	Visit 11	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
12-1201	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex	Absent	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				10
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
12-1201	NDisc plus	ES/SAF/FAS	Unscheduled	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
12-1201	NDisc plus	ES/SAF/FAS	Visit 4	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Absent	
					Quadriceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive	Positive	
				Walking range(m)				4000
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
12-1201	NDisc plus	ES/SAF/FAS	Visit 5	Reflexes	Ankle reflex Quadriceps reflex	Reduced ND	Reduced Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Reduced Normal	
					Cauda equina syndrome			N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
12-1201	NDisc plus	ES/SAF/FAS	Visit 7	Motor deficits	Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Reduced	Reduced	
					Quadriiceps reflex	Reduced	Reduced	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive	Positive	
				Walking range(m)				7000
		Unscheduled		Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
12-1201	NDisc plus	ES/SAF/FAS	Unscheduled	Quality	Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit	Partial sensory deficit	
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	
				Cauda equina syndrome				N
				Walking range(m)				1500
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Always	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Absent Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
12-1201	NDisc plus	ES/SAF/FAS	Visit 11	Cauda equina syndrome				N
				Sciatic stretch test		Positive	Positive	
				Walking range(m)				4000

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1301	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality	Numb nerve roots	Intermittent	
					Reflexes	Ankle reflex Quadriiceps reflex	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				200
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1301	NDisc plus	ES/SAF/FAS	Visit 3a	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				3000
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Quality		Intermittent	
					Reflexes		Normal	
				Cauda equina syndrome	Ankle reflex		Normal	
					Quadriceps reflex		Normal	
					Cauda equina syndrome			
			Visit 5	Motor deficits	Sciatic stretch test		Negative	
					Walking range(m)		Negative	
							4000	
					Cauda equina syndrome			
					Sciatic stretch test		Negative	
				Sensory deficits	Walking range(m)		4000	
					Cauda equina syndrome			
					Sciatic stretch test		Negative	
				Sensory deficits	Walking range(m)		4000	
					Cauda equina syndrome			
					Sciatic stretch test		Negative	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1301	NDisc plus	ES/SAF/FAS	Visit 5	Walking range(m)				3000
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				2000
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1301	NDisc plus	ES/SAF/FAS	Visit 7	Sensory deficits	Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
			Visit 8	Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				4000
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Intermittent	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				2500
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1301	NDisc plus	ES/SAF/FAS	Visit 11	Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1302	NDisc plus	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
					Numb nerve roots		Intermittent	
					Ankle reflex		Normal	
				Reflexes	Quadriceps reflex		Normal	
				Cauda equina syndrome		N		
				Sciatic stretch test		Positive		
				Walking range(m)		20		
			Visit 3a	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
					Numb nerve roots		Intermittent	
					Ankle reflex		Normal	
				Reflexes	Quadriceps reflex		Normal	
				Cauda equina syndrome		N		
				Sciatic stretch test		Negative		
				Walking range(m)		Unlimited		
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1302	NDisc plus	ES/SAF/FAS	Visit 4	Motor deficits	Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1302	NDisc plus	ES/SAF/FAS	Visit 6	Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor Ankle extensor Hip flexor Knee extensor Big toe extensor	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5) No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
				Quality	Numb nerve roots		Always	
				Reflexes	Ankle reflex Quadriceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1302	NDisc plus	ES/SAF/FAS	Visit 8	Reflexes	Ankle reflex Quadriiceps reflex	Normal Normal	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root L5		Partial sensory deficit	
					Quality	Numb nerve roots	Always	
					Reflexes	Ankle reflex Quadriiceps reflex	Normal Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1303	SC	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Nerve root L5		Partial sensory deficit	
				Quality	Tingle nerve roots		Always	
					Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	Very few deficits (4)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
					Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Negative
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)		No deficits (Normal - 5)

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1303	SC	ES/SAF/FAS	Visit 5	Motor deficits	Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 6	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1303	SC	ES/SAF/FAS	Visit 6	Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1303	SC	ES/SAF/FAS	Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Partial sensory deficit	
				Quality	Tingle nerve roots		Always	
					Numb nerve roots		Always	
				Reflexes	Ankle reflex	Normal	Reduced	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1303	SC	ES/SAF/FAS	Unscheduled	Reflexes	Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test			Positive	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1303	SC	ES/SAF/FAS	Unscheduled	Motor deficits	Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriciceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1304	NDisc basic	ES/SAF/FAS	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	Partial sensory deficit		
				Quality	Tingle nerve roots	Intermittent		
					Numb nerve roots	Always		
					Hypersensitive nerve roots	Intermittent		
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Positive		
				Walking range(m)				0300
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1304	NDisc basic	ES/SAF/FAS	Unscheduled	Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Sensory deficits			
					Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 4	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1304	NDisc basic	ES/SAF/FAS	Visit 4	Motor deficits	Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				
				Walking range(m)				Unlimited
			Visit 5	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1304	NDisc basic	ES/SAF/FAS	Visit 5	Quality	Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
			Visit 6	Walking range(m)				Unlimited
				Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1304	NDisc basic	ES/SAF/FAS	Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 7	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1304	NDisc basic	ES/SAF/FAS	Visit 7	Sensory deficits	Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 8	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1304	NDisc basic	ES/SAF/FAS	Visit 8	Walking range(m)				Unlimited
			Unscheduled	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	
					Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited
			Visit 11	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1	None	None	
					Nerve root S2	None	None	
					Nerve root L5	None	None	
					Nerve root L4	None	None	

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1304	NDisc basic	ES/SAF/FAS	Visit 11	Sensory deficits	Nerve root L3	None	None	
					Nerve root L2	None	None	
					Nerve root L1	None	None	
				Quality	Tingle nerve roots	None	None	
					Numb nerve roots	None	None	
					Hypersensitive nerve roots	None	None	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriiceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test		Negative	Negative	
				Walking range(m)				Unlimited

Listing 16.2.2.3: Neurological Status (Jenny Scale) - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter Category	Parameter	Left	Right	General
13-1305	NDisc plus	ES/SAF	Visit 1	Motor deficits	Ankle flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Ankle extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Hip flexor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Knee extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
					Big toe extensor	No deficits (Normal - 5)	No deficits (Normal - 5)	
				Sensory deficits	Nerve root S1		Complete sensory deficit	
					Quality		Intermittent Always	
				Reflexes	Ankle reflex	Normal	Normal	
					Quadriceps reflex	Normal	Normal	
				Cauda equina syndrome				N
				Sciatic stretch test				Positive
				Walking range(m)				0050

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
01/0103	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 1	17OCT2012	25.0	2.0	Abnormal / PROTECTIVE LIMPING	Abnormal / PAIN AGGRAVATION UNDER PERCUSSION
	ND basic	ES/SAF/FAS	VISIT 3A	14JAN2013	Not done	Not done	Abnormal / RIGHT KNEE INSTABILITY	Normal
	ND basic	ES/SAF/FAS	VISIT 4	20FEB2013	27.0	5.6	Abnormal / Limping and relieving posture	Abnormal / zygapophysial joint degeneration
	ND basic	ES/SAF/FAS	VISIT 5	17APR2013	20.0	4.5	Abnormal / Limping and relieving posture	Normal
	ND basic	ES/SAF/FAS	VISIT 6	18JUL2013	28.0	6.0	Abnormal / protective limp	Abnormal / pressure pain
	ND basic	ES/SAF/FAS	VISIT 7	08JAN2014	18.0	4.5	Abnormal / relieving posture	Abnormal / facet-pressure, paravertebral hardened muscles
	ND basic	ES/SAF/FAS	VISIT 8	16FEB2015	22.0	5.0	Abnormal / limping (patellaarthrosis)	Normal
01/0104	ND basic	ES/SAF/FAS	VISIT 11	17JAN2018	29.0	3.9	Abnormal / knee pain	Abnormal / pressure pain
	ND basic	ES/SAF/FAS	VISIT 1	22OCT2012	37.0	3.0	Normal	Normal
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	23OCT2012	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 3A	21JAN2013	20.0	3.9	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	27FEB2013	22.0	4.0	Normal	Abnormal / wound pressure pain
	ND basic	ES/SAF/FAS	VISIT 5	26APR2013	15.0	5.0	Normal	Abnormal / pressure pain
	ND basic	ES/SAF/FAS	VISIT 6	31JUL2013	38.0	2.5	Normal	Abnormal / pressure pain
	ND basic	ES/SAF/FAS	VISIT 7	15JAN2014	28.0	2.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	23JUN2015	29.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	24JAN2018	0.0	6.0	Normal	Normal
01/0106	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	26NOV2012	30.0	1.8	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	18FEB2013	23.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	03APR2013	16.0	3.7	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	22MAY2013	12.0	3.2	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	21AUG2013	0.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	19FEB2014	7.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	18FEB2015	17.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	14FEB2018	1.0	5.0	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
01/0107	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	08JAN2013	10.0	3.5	Abnormal / protective limping	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	08APR2013	0.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	15MAY2013	0.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	03JUL2013	0.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	25SEP2013	0.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	26MAR2014	0.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	08APR2015	0.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	11APR2018	0.0	5.0	Normal	Normal
01/0108	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	09JAN2013	17.0	5.8	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	15APR2013	14.5	6.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	29MAY2013	12.0	5.8	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	11JUL2013	14.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	01OCT2013	7.0	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	02APR2014	7.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	16APR2015	0.0	6.5	Normal	Normal
01/0110	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 1	22JAN2013	31.0	3.0	Abnormal / protective limping	Normal
	ND basic	ES/SAF/FAS	VISIT 3A	22APR2013	22.0	4.2	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	05JUN2013	2.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	31JUL2013	4.0	5.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	15OCT2013	2.0	3.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 7	09APR2014	1.0	5.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	22APR2015	1.0	4.0	Normal	Normal
01/0111	ND plus	ES/SAF/FAS	VISIT 1	11MAR2013	40.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	11MAR2013	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 3A	10JUN2013	22.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	25JUL2013	23.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	04SEP2013	20.0	5.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	18DEC2013	21.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	04JUN2014	24.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	10JUN2015	19.0	5.5	Normal	Normal
01/0111	ND plus	ES/SAF/FAS	VISIT 11	30MAY2018	15.5		Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
01/0112	ND basic	ES/SAF	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF	VISIT 1	25MAR2013	40.0	2.0	Normal	Normal
	ND basic	ES/SAF	UNSCHEDULED	02APR2013	Not done	Not done	Not done	Not done
	ND basic	ES/SAF	VISIT 11	08JUL2013	6.5	2.0	Normal	Normal
01/0113	ND basic	ES/SAF/FAS	VISIT 1	22MAY2013	12.0	4.6	Abnormal / protective limping	Normal
	ND basic	ES/SAF/FAS	VISIT 3A	05AUG2013	5.0	7.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	10SEP2013	0.0	4.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	06NOV2013	3.0	5.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	28JAN2014	0.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	11JUL2014	14.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 7	30JUL2014	29.0	2.0	Abnormal / protective limb	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	04AUG2014	Not done	Not done	Abnormal / protective limb	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	03SEP2014	21.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	02OCT2014	Not done	Not done	Abnormal / PROTECTIVE LIMB	Abnormal / PAINFUL
	ND basic	ES/SAF/FAS	VISIT 8	22JUL2015	0.0	4.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	17OCT2018	0.0	3.0	Normal	Normal
01/0114	ND basic	ES/SAF/FAS	VISIT 1	09JUN2013	Not done	Not done	Not done	Abnormal / paravertebral muscle hardenings
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	10JUN2013	36.0	4.0	Abnormal / relieving posture	Not done
	ND basic	ES/SAF/FAS	VISIT 3A	10SEP2013	26.0	5.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	16OCT2013	18.0	1.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	10DEC2013	17.0	6.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	12MAR2014	14.0	4.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 7	10SEP2014	11.0	6.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	09SEP2015	12.0	5.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	05SEP2018	19.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	05SEP2018	19.0	4.0	Normal	Normal
01/0115	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	11JUN2013	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	16SEP2013	23.0	1.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	30OCT2013	15.0	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	12DEC2013	19.0	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	11MAR2014	15.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	25SEP2014	12.0	5.0	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
01/0115	ND plus	ES/SAF/FAS	VISIT 8	16SEP2015	6.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	10OCT2018	13.0	5.0	Normal	Normal
01/0116	ND basic	ES/SAF	VISIT 1	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF	BASELINE (VISIT 2A)	17JUN2013	60.0	1.0	Normal	Normal
01/0118	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	UNSCHEDULED	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	08JUL2013	20.0	1.0	Abnormal / PROTECTIVE LIMB	Abnormal / PRESSURE PAIN L5/S1 RIGHT
	ND plus	ES/SAF/FAS	VISIT 3A	07OCT2013	22.0	1.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	20NOV2013	28.0	3.0	Abnormal / PROTECTIVE LIMB	Normal
	ND plus	ES/SAF/FAS	VISIT 5	07JAN2014	17.0	4.5	Abnormal / Slight protective limb	Normal
	ND plus	ES/SAF/FAS	VISIT 6	25MAR2014	12.0	4.5	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	28MAY2014	Not done	Not done	Abnormal / MILD LIMPING	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	09JUL2014	20.0	3.0	Abnormal / MILD LIMPING	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	20AUG2014	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	18SEP2014	Not done	Not done	Abnormal / relieving posture	Normal
	ND plus	ES/SAF/FAS	VISIT 7	08OCT2014	23.0	4.5	Abnormal / protective limb	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	22OCT2014	15.0	3.5	Abnormal / protective limb	Normal
	ND plus	ES/SAF/FAS	VISIT 8	07OCT2015	27.0	4.5	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	15JUN2016	Not done	Not done	Abnormal / PROTECTIVE LIMP	Normal
	ND plus	ES/SAF/FAS	VISIT 11	03OCT2018	23.5	4.0	Abnormal / Claudicatio spinalis	Normal
01/0119	ND basic	ES/SAF/FAS	VISIT 1	22JUL2013	30.0	2.0	Abnormal / relieving posture	Abnormal / Percussion tenderness none / Pressure pain paraesthesia
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	22JUL2013	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 3A	14OCT2013	10.0	2.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	19NOV2013	6.0	3.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	14JAN2014	5.0	5.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	03APR2014	4.0	4.0	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
01/0119	ND basic	ES/SAF/FAS	UNSCHEDULED	14JUL2014	Not done	Not done	Abnormal / protective limb	Abnormal / paravertebral re L4/L5
	ND basic	ES/SAF/FAS	VISIT 7	15OCT2014	5.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	14OCT2015	5.0	3.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	10OCT2018	11.5	5.0	Normal	Normal
01/0121	ND plus	ES/SAF/FAS	VISIT 1	18SEP2013	29.0	2.0	Normal	Abnormal / PARAVERTEBRAL PRESSURE PAIN INCREASED LUMBOISCHALGIA
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	14OCT2013	26.0	1.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	13JAN2014	11.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	18FEB2014	10.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	08APR2014	4.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	14JUL2014	3.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	21JAN2015	6.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	13JAN2016	10.0	4.5	Normal	Normal
01/0122	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	25SEP2013	20.0	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	16DEC2013	23.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	29JAN2014	16.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	18MAR2014	15.5	4.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	11JUN2014	11.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	17DEC2014	11.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	16DEC2015	12.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	15JUN2016	Not done	Not done	Abnormal / PROTECTIVE LIMP	Normal
	ND plus	ES/SAF/FAS	VISIT 11	19DEC2018	11.5		Normal	Normal
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
01/0123	ND plus	ES/SAF/FAS	UNSCHEDULED	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	15SEP2014	12.0	4.5	Abnormal / PROTECTIVE LIMB	Abnormal / PRESSURE PAIN RIGHT
	ND plus	ES/SAF/FAS	VISIT 3A	18DEC2014	28.0	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	28JAN2015	24.0	2.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	20MAR2015	21.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	02JUL2015	18.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	17DEC2015	19.0	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	07DEC2016	19.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	06MAR2017	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	UNSCHEDULED	09JUN2017	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	UNSCHEDULED	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	15SEP2014	12.0	4.5	Abnormal / PROTECTIVE LIMB	Abnormal / PRESSURE PAIN RIGHT

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
01/0123	ND plus	ES/SAF/FAS	UNSCHEDULED	24MAY2018	Not done	Not done	Not done	Not done
01/0124	ND plus	ES/SAF	VISIT 1	01OCT2014	43.0	2.5	Abnormal / PROTECTIVE LIMB	Normal
	ND plus	ES/SAF	BASELINE (VISIT 2A)	05NOV2014	38.0	3.5	Abnormal / protective limb	Normal
01/0125	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	06OCT2014	37.0	2.0	Abnormal / protective limb	Normal
	SC	ES/SAF/FAS	VISIT 4	19NOV2014	33.0	3.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	07JAN2015	12.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 6	25MAR2015	8.0	3.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 7	30SEP2015	0.0	4.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	28SEP2016	0.0	5.5	Normal	Normal
	SC	ES/SAF/FAS	UNSCHEDULED	10JAN2018	Not done	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 11	02OCT2019	0.0	4.5	Normal	Normal
01/0126	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 1	06OCT2014	44.0	2.0	Abnormal / protective limb	Normal
	ND basic	ES/SAF/FAS	VISIT 3A	07JAN2015	33.0	2.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	16FEB2015	24.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	04MAR2015	Not done	Not done	Abnormal / prot. limping	Abnormal / pressure pain medial
	ND basic	ES/SAF/FAS	VISIT 5	08APR2015	23.0	2.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	30JUN2015	11.0	3.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 7	12JAN2016	8.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	11JAN2017	5.0	2.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	11DEC2019	5.0	2.5	Normal	Normal
01/0127	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	17OCT2014	33.0	2.5	Abnormal / PROTECTIVE LIMB	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	08JAN2015	30.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	19FEB2015	6.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	08APR2015	0.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	01JUL2015	0.0	4.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	13JAN2016	0.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	11JAN2017	0.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	14FEB2018	2.0	5.0	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
01/0127	ND plus	ES/SAF/FAS	VISIT 11	18DEC2019	2.0	3.0	Normal	Normal
01/0128	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	20OCT2014	55.0	1.0	Abnormal / PROTECTIVE LIMB	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	12JAN2015	41.0	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	24FEB2015	34.0	3.5	Normal	Abnormal / pressure pain medial
	ND plus	ES/SAF/FAS	VISIT 5	14APR2015	33.0	2.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	14JUL2015	27.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	14JAN2016	28.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	25JAN2017	20.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	01MAR2019	Not done	Not done	Normal	Abnormal / facette joint L5/S1
	ND plus	ES/SAF/FAS	VISIT 11	18DEC2019	19.5	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	18DEC2019	19.5	3.0	Normal	Normal
01/0129	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	UNSCHEDULED	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	28OCT2014	Not done	Not done	Abnormal / paresis	Abnormal / pressure pain, right
	SC	ES/SAF/FAS	VISIT 4	10DEC2014	18.0	3.0	Abnormal / Paresis dorsal flexion right	Normal
	SC	ES/SAF/FAS	VISIT 5	21JAN2015	2.0	4.0	Abnormal / PARESIS DORSAL FLEX. RIGHT	Normal
	SC	ES/SAF/FAS	VISIT 6	14APR2015	8.0	4.0	Abnormal / PARESIS DORSAL FLEXOR RIGHT	Normal
	SC	ES/SAF/FAS	VISIT 7	21OCT2015	3.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	05OCT2016	15.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	UNSCHEDULED	15FEB2019	Not done	Not done	Abnormal / poor gait	Not done
	SC	ES/SAF/FAS	VISIT 11	02OCT2019	20.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 11	02OCT2019	20.0	4.0	Normal	Normal
01/0130	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 1	19NOV2014	16.0	2.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 3A	03FEB2015	0.0	4.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	17MAR2015	0.0	5.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	27APR2015	0.0	3.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	29JUL2015	0.0	7.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 7	20JAN2016	0.0	3.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	01FEB2017	0.0	4.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	22JAN2020	3.0	5.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	22JAN2020	3.0	5.0	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
01/0131	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	28NOV2014	71.0	0.5	Abnormal / protective limb	Abnormal / pressure pain right
	ND plus	ES/SAF/FAS	VISIT 3A	18FEB2015	0.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	09APR2015	0.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	27MAY2015	0.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	18AUG2015	0.0	4.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	18FEB2016	0.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	15MAR2017	0.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	29JAN2020	2.0	4.5	Normal	Normal
01/0132	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	01DEC2014	51.0	2.5	Abnormal / protective limb	Normal
	SC	ES/SAF/FAS	VISIT 4	13JAN2015	14.0	5.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	18MAR2015	13.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 6	20MAY2015	10.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 7	25NOV2015	13.0	4.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	23NOV2016	13.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 11	20NOV2019	10.0	5.0	Normal	Normal
01/0133	ND plus	ES/SAF	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF	UNSCHEDULED	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF	VISIT 1	15DEC2014	31.0	3.0	Abnormal / PROTECTIVE LIMB	Normal
01/0134	ND basic	ES/SAF	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF	VISIT 1	16DEC2014	40.0	3.5	Abnormal / PROTECTIVE LIMB	Normal
	ND basic	ES/SAF	UNSCHEDULED	15JAN2015	Not done	Not done	Not done	Not done
01/0135	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	14JAN2015	11.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	07APR2015	16.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	26MAY2015	6.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	07JUL2015	4.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	06OCT2015	0.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	06APR2016	0.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	03MAY2017	0.0	7.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	27MAY2020	0.0	8.0	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
01/0136	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 1	20FEB2015	16.0	3.5	Abnormal / protective limp	Normal
	ND basic	ES/SAF/FAS	VISIT 3A	02JUN2015	23.0	3.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	15JUL2015	7.0	5.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	26AUG2015	2.0	4.0	Abnormal / protective limp	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	21OCT2015	0.0	4.0	Abnormal / protective limp	Normal
	ND basic	ES/SAF/FAS	VISIT 6	24NOV2015	0.0	4.0	Abnormal / protective limping	Normal
	ND basic	ES/SAF/FAS	VISIT 7	25MAY2016	0.0	4.0	Abnormal / protective limp	Normal
01/0137	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	25FEB2015	0.0	1.5	Abnormal / protective limb	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	01JUN2015	10.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	16JUL2015	0.0	4.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	25AUG2015	0.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	18NOV2015	0.0	4.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	01JUN2016	0.0	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	07JUN2017	0.0	5.0	Normal	Normal
01/0138	ND plus	ES/SAF/FAS	VISIT 11	24JUN2020	0.0	3.0	Normal	Normal
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	05MAR2015	21.0	3.0	Abnormal / Paresis	Normal
	SC	ES/SAF/FAS	VISIT 4	23APR2015	24.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	05JUN2015	13.0	3.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 6	15SEP2015	8.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 7	24FEB2016	8.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	08FEB2017	13.0	3.5	Normal	Normal
01/0139	SC	ES/SAF/FAS	VISIT 11	12FEB2020	15.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	09MAR2015	38.0	5.5	Abnormal / Paresis	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	02JUN2015	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	14JUL2015	0.0	4.5	Normal	Normal
01/0139	ND plus	ES/SAF/FAS	VISIT 5	26AUG2015	0.0	6.0	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
01/0139	ND plus	ES/SAF/FAS	VISIT 6	02DEC2015	0.0	6.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	15JUN2016	0.0	6.0	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	21DEC2016	Not done	Not done	Abnormal / protective limp	Normal
	ND plus	ES/SAF/FAS	VISIT 8	07JUN2017	0.0	3.5	Normal	Normal
01/0140	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 1	11MAY2015	11.5	2.5	Normal	Abnormal / local pressure pain
	ND basic	ES/SAF/FAS	VISIT 3A	10AUG2015	12.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	22SEP2015	11.0	3.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	04NOV2015	10.0	4.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	08FEB2016	8.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 7	27JUL2016	8.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	26JUL2017	8.0	4.0	Normal	Normal
01/0141	SC	ES/SAF/FAS	VISIT 1	21MAY2015	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	26MAY2015	49.0	1.5	Abnormal / protectiv limp	Normal
	SC	ES/SAF/FAS	VISIT 4	13JUL2015	53.0	1.5	Abnormal / protective limp	Normal
	SC	ES/SAF/FAS	VISIT 5	02SEP2015	46.0	2.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 6	11NOV2015	28.0	2.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 7	18MAY2016	24.0	2.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	10MAY2017	15.0	5.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 11	24JUN2020	7.0	5.0	Normal	Normal
	SC	ES/SAF/FAS	UNSCHEDULED	03MAR2021	0.0	5.0	Normal	Normal
	SC	ES/SAF/FAS	UNSCHEDULED	03MAR2021	0.0	5.0	Normal	Normal
01/0142	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	26MAY2015	13.0	2.5	Abnormal / Paresis S1 re	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	24AUG2015	0.0	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	05OCT2015	0.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	25NOV2015	0.0	4.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	02MAR2016	0.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	31AUG2016	0.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	30AUG2017	0.0	6.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	05AUG2020	5.0	7.0	Normal	Normal
01/0143	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	15JUN2015	35.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	22SEP2015	33.0	3.0	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
01/0143	ND plus	ES/SAF/FAS	VISIT 4	02NOV2015	14.0	4.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	16DEC2015	24.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	09MAR2016	26.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	07SEP2016	27.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	23AUG2017	20.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	16SEP2020	5.0	5.0	Normal	Normal
01/0144	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 1	22JUN2015	56.0	2.5	Normal	Abnormal / pressure pain left
	ND basic	ES/SAF/FAS	VISIT 3A	22SEP2015	16.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	03NOV2015	0.0	5.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	17DEC2015	0.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	30MAR2016	0.0	5.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 7	21SEP2016	0.0	3.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	30AUG2017	0.0	3.5	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	23JAN2019	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	UNSCHEDULED	23MAY2019	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	09SEP2020	0.0	4.7	Normal	Normal
01/0145	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	14JUL2015	0.0	6.0	Normal	Abnormal / pressure pain right
	ND plus	ES/SAF/FAS	UNSCHEDULED	14SEP2015	45.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	05OCT2015	28.0	4.0	Abnormal / protective limp	Normal
	ND plus	ES/SAF/FAS	VISIT 4	19NOV2015	36.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	05JAN2016	17.0	6.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	05APR2016	23.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	05OCT2016	15.0	4.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	20SEP2017	23.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	30SEP2020	0.0	3.0	Normal	Normal
01/0146	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	15JUL2015	40.0	1.0	Abnormal / protective limp	Normal
	SC	ES/SAF/FAS	VISIT 4	27AUG2015	24.0	3.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	13OCT2015	16.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 6	19JAN2016	18.0	3.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 7	06JUL2016	16.0	3.5	Abnormal / PROTECTIVE LIMP	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
01/0146	SC	ES/SAF/FAS	VISIT 8	21JUN2017	12.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 11	26AUG2020	5.0	7.0	Normal	Normal
01/0147	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	19AUG2015	0.0	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	17NOV2015	0.0	2.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	05JAN2016	0.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	09FEB2016	0.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	11MAY2016	0.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	16NOV2016	0.0	2.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	15NOV2017	0.0	5.0	Normal	Normal
01/0148	ND plus	ES/SAF/FAS	VISIT 11	04NOV2020	2.0	4.5	Normal	Normal
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	21OCT2015	27.0	4.0	Abnormal / protective limp	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	11JAN2016	10.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	24FEB2016	16.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	13APR2016	10.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	20JUN2016	8.0	4.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	14DEC2016	0.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	13DEC2017	4.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	13FEB2019	Not done	Not done	Normal	Normal
01/0149	ND plus	ES/SAF/FAS	VISIT 11	08FEB2021	7.5	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	01DEC2015	15.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	01MAR2016	8.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	13APR2016	0.0	5.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	01JUN2016	0.0	5.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	14SEP2016	0.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	15MAR2017	0.0	4.0	Normal	Normal
01/0150	ND plus	ES/SAF/FAS	VISIT 8	14MAR2018	0.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	24FEB2021	7.5	3.0	Normal	Normal
01/0151	ND plus	ES	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES	VISIT 1	02FEB2016	15.0	4.0	Normal	Normal
01/0151	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 1	01MAR2016	Not done	Not done	Abnormal / Protective Limp	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
01/0151	ND basic	ES/SAF/FAS	VISIT 3A	07JUN2016	27.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	13JUL2016	28.0	4.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	07SEP2016	25.0	4.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	30NOV2016	21.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 7	31MAY2017	23.0	4.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	02MAY2018	20.0	5.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	12MAY2021	5.0	7.0	Normal	Normal
01/0152	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	02MAR2016	0.0	3.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 4	21APR2016	21.0	4.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	25MAY2016	22.0	5.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 6	24AUG2016	16.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 7	22FEB2017	7.0	5.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	07MAR2018	1.0	4.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 11	10MAR2021	5.0	5.0	Normal	Normal
01/0153	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	UNSCHEDULED	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 1	18MAR2016	34.0	2.0	Abnormal / PROTECTIVE LIMP	Abnormal / Pressure Pain Right
	ND basic	ES/SAF/FAS	VISIT 3A	07JUN2016	27.0	3.0	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	22JUN2016	Not done	Not done	Abnormal / PROTECTIVE LIMP	Abnormal / PRESSURE PAIN
	ND basic	ES/SAF/FAS	VISIT 4	20JUL2016	30.0	3.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	07SEP2016	0.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	30NOV2016	22.0	6.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 7	31MAY2017	21.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	26JUL2017	10.0	5.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	02MAY2018	6.0	5.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	14JUN2021	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	12FEB2013				
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	12FEB2013	10.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	07MAY2013	0.0	15.0	Normal	Normal
02/0201	ND plus	ES/SAF/FAS	VISIT 4	20JUN2013	5.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	31JUL2013	0.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	29OCT2013	0.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	06MAY2014	0.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	02JUN2015	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	28DEC2015	Not done	Not done	Not done	Not done

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
02/0201	ND plus	ES/SAF/FAS	VISIT 11	29MAY2018	10.0	Not done	Normal	Normal
02/0202	ND basic	ES/SAF	VISIT 1	19MAR2013	Not done	Not done	Abnormal / Lumbar Hyperlordosis	Normal
02/0203	ND basic	ES/SAF/FAS	VISIT 1	27MAR2013	40.0	Not done	Abnormal / walk on crutches	Normal
	ND basic	ES/SAF/FAS	VISIT 3A	25JUN2013	0.0	5.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	13AUG2013	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	24SEP2013	40.0	9.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	10DEC2013	0.0	9.0	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	26FEB2014	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	05MAR2014	Not done	Not done	Abnormal / walking unloaded right leg	Abnormal / light tenderness on palpation in lumbosacral junction right
	ND basic	ES/SAF/FAS	VISIT 7	26JUN2014	0.0	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	24JUN2015	20.0	10.0	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	10FEB2016	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	20JUL2016	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	UNSCHEDULED	11AUG2016	Not done	Not done	Not done	Not done
02/0204	ND basic	ES/SAF	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF	VISIT 1	17APR2013	Not done	Not done	Abnormal / limping	Normal
02/0205	ND basic	ES/SAF/FAS	VISIT 1	17APR2013	30.0	Not done	Abnormal / Pain exacerbation	Abnormal / Pain exacerbation
	ND basic	ES/SAF/FAS	VISIT 3A	30JUL2013	15.0	5.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	17SEP2013	30.0	9.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	28OCT2013	30.0	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	23JAN2014	20.0	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 7	12AUG2014	25.0	9.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	21AUG2015	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	28AUG2018	20.0	9.0	Normal	Normal
02/0206	ND plus	ES/SAF/FAS	VISIT 1	27JUN2013	Not done	Not done	Abnormal / Pain-Exacerbation	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	07OCT2013	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	20NOV2013	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 5	03JAN2014	10.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	07MAR2014	7.5	9.0	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
02/0206	ND plus	ES/SAF/FAS	VISIT 7	05AUG2014	12.0	9.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	30AUG2018	5.0	Not done	Normal	Normal
02/0207		ES	VISIT 1	23JUL2013	Not done	Not done	Abnormal / Putting less weight on right leg	Abnormal / Lower lumbar spine, pressure pain above sacrailliac joint, right more then left
02/0208	ND plus	ES/SAF/FAS	VISIT 1	11SEP2013	10.0	5.0	Abnormal / limping	Abnormal / little Percussion Pain
	ND plus	ES/SAF/FAS	VISIT 3A	09DEC2013	15.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	16DEC2013	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 4	22JAN2014	15.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	25MAR2014	25.0	9.0	Abnormal / knee problems	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	01APR2014	Not done	Not done	Abnormal / upper part of the body crooked to the left	Abnormal / left paravertebral lower lumbar spine
	ND plus	ES/SAF/FAS	VISIT 6	28MAY2014	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	30DEC2014	16.0	9.0	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	01SEP2015	15.0	9.0	Abnormal / Limb on left side	Abnormal / pressure pain left side
	ND plus	ES/SAF/FAS	UNSCHEDULED	21SEP2015	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 8	17DEC2015	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 11	27DEC2018	10.0	Not done	Normal	Normal
02/0209	ND plus	ES/SAF/FAS	VISIT 1	22OCT2014	20.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	29JAN2015	10.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	24MAR2015	15.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	29APR2015	15.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	16JUL2015	10.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	05NOV2015	20.0	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 7	23FEB2016	15.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	19JAN2017	6.0	9.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	30DEC2019	10.0	Not done	Normal	Normal
02/0210		ES	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
		ES	VISIT 1	12NOV2014	60.0	2.0	Normal	Normal
02/0211	ND basic	ES/SAF	VISIT 1	10DEC2014	Not done	Not done	Not done	Not done
	ND basic	ES/SAF	VISIT 3A	04MAR2015	5.0	9.0	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
02/0212	SC	ES/SAF/FAS	VISIT 1	15DEC2014	Not done	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 4	30JAN2015	10.0	10.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	10APR2015	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 6	25JUN2015	20.0	3.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 7	28JAN2016	25.0	9.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	28DEC2016	10.0	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 11	27DEC2019	Not done	Not done	Normal	Normal
02/0213	ND plus	ES/SAF	BASELINE (VISIT 2A)	17DEC2014	Not done	Not done	Not done	Not done
02/0214	ND plus	ES/SAF/FAS	VISIT 1	24FEB2015	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	27MAY2015	5.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	23JUL2015	5.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	03DEC2015	10.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	26MAY2016	7.0	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	15OCT2020	Not done	Not done	Normal	Normal
02/0215		ES	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
		ES	VISIT 1	04MAR2015	15.0	0.0	Normal	Normal
02/0216	ND plus	ES/SAF/FAS	VISIT 1	27APR2015	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	22JUL2015	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	UNSCHEDULED	29JUL2015	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	UNSCHEDULED	07AUG2015	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 5	21OCT2015	Not done	Not done	Normal	Normal
02/0217	SC	ES/SAF/FAS	VISIT 1	27MAY2015	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 4	14JUL2015	Not done	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	30AUG2015	Not done	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 6	08DEC2015	0.0	9.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 7	11MAY2016	Not done	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	27APR2017	Not done	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 11	01JUL2020	10.0	Not done	Normal	Normal
02/0218	ND basic	ES/SAF	BASELINE (VISIT 2A)	29JUN2015	15.0	Not done	Normal	Normal
02/0219	ND basic	ES/SAF/FAS	VISIT 1	10JUN2015	Not done	Not done	Abnormal / Analgetic gait	Abnormal / Pressure pain
	ND basic	ES/SAF/FAS	VISIT 3A	24SEP2015	10.0	5.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	04NOV2015	10.0	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	17DEC2015	20.0	9.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	04APR2016	10.0	Not done	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
02/0219	ND basic	ES/SAF/FAS	VISIT 7	22AUG2016	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	20SEP2017	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	26AUG2020	Not done	Not done	Not done	Not done
02/0220	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	12AUG2015	Not done	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 4	29SEP2015	20.0	6.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	17NOV2015	10.0	4.0	Not done	Not done
	SC	ES/SAF/FAS	VISIT 6	26JAN2016	10.0	9.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 7	04AUG2016	10.0	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	19JUL2017	5.0	5.0	Normal	Abnormal / Left
	SC	ES/SAF/FAS	VISIT 11	02SEP2020	Not done	Not done	Not done	Lumbo-sacral Not done
02/0221	ND plus	ES/SAF	VISIT 1	31AUG2015	Not done	Not done	Normal	Normal
	ND plus	ES/SAF	VISIT 3A	10DEC2015	Not done	Not done	Normal	Normal
02/0222	ND plus	ES/SAF	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF	VISIT 1	09SEP2015	Not done	Not done	Abnormal / Subside during tiptoeing right	Normal
02/0223	ND basic	ES/SAF/FAS	VISIT 1	28DEC2015	Not done	Not done	Normal	Abnormal / minor pressure pain
	ND basic	ES/SAF/FAS	VISIT 3A	21MAR2016	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	27APR2016	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 5	05JUL2016	6.0	9.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	24AUG2016	0.0	1.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 7	15MAR2017	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 8	07MAR2018	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	03MAR2021	Not done	Not done	Not done	Not done
02/0224	ND plus	ES/SAF	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF	VISIT 1	28DEC2015	Not done	Not done	Not done	Not done
04/0401	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	24JUN2015	25.0	3.0	Abnormal / slowly	Normal
	SC	ES/SAF/FAS	VISIT 4	11AUG2015	20.0	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	08OCT2015	0.0	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 6	16DEC2015	0.0	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 7	21JUN2016	0.0	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	05JUL2017	0.0	Not done	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
04/0401	SC	ES/SAF/FAS	VISIT 11	27JUL2020	0.0	Not done	Normal	Normal
06/0602	ND plus	ES/SAF/FAS	VISIT 1	22JUL2013	10.0	4.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	04NOV2013	10.0	4.0	Normal	Abnormal / light pain lumbar and ISG left = sacroiliac joint
	ND plus	ES/SAF/FAS	VISIT 4	18DEC2013	10.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	12FEB2014	10.0	14.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	22APR2014	8.0	4.0	Normal	Abnormal / light pain
	ND plus	ES/SAF/FAS	VISIT 7	23OCT2014	9.0	1.2	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	18NOV2015	2.0	3.0	Normal	Normal
06/0604	ND basic	ES/SAF	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF	VISIT 1	27OCT2014	63.0	1.0	Normal	Normal
06/0605	ND plus	ES/SAF	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF	VISIT 1	10DEC2014	32.0	3.5	Normal	Abnormal / L5/S1 medial
06/0606	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	15DEC2014	0.0	6.5	Normal	Abnormal / Lumbosacral ISG right
	SC	ES/SAF/FAS	VISIT 4	10FEB2015	6.5	5.5	Normal	Abnormal / ISG right and left
	SC	ES/SAF/FAS	VISIT 5	12MAR2015	Not done	1.5	Normal	Abnormal / Scare from surgical treatment
	SC	ES/SAF/FAS	VISIT 6	03JUN2015	8.0	5.0	Normal	Abnormal / Distal part of the wound
	SC	ES/SAF/FAS	VISIT 7	03DEC2015	3.0	6.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	24NOV2016	1.0	6.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 11	03DEC2019	0.0	6.0	Normal	Normal
06/0607	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	19JAN2015	12.0	4.5	Normal	Abnormal / ISG right
	ND plus	ES/SAF/FAS	VISIT 3A	14APR2015	10.0	4.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	01JUN2015	10.0	4.5	Normal	Abnormal / Wound
	ND plus	ES/SAF/FAS	VISIT 5	21JUL2015	5.0	5.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	06OCT2015	9.5	5.0	Normal	Abnormal / LW 5
	ND plus	ES/SAF/FAS	VISIT 7	05APR2016	3.5	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	05APR2017	0.0	4.8	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	28MAR2018	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 11	16MAR2020	0.0	3.0	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
06/0608	SC	ES/SAF	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF	VISIT 1	27JAN2015	22.0	5.5	Normal	Normal
06/0609	ND basic	ES/SAF	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF	VISIT 1	15APR2015	52.0	3.0	Abnormal / claudication right	Abnormal / LWS
06/0610	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	24JUN2015	46.0	2.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	07SEP2015	40.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	26OCT2015	22.0	6.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	14DEC2015	15.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	19JAN2016	41.0	2.0	Abnormal / limping left	Abnormal / tenderness L5/S1 left
	ND plus	ES/SAF/FAS	VISIT 6	16MAR2016	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 7	30AUG2016	18.0	4.3	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	10OCT2017	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 11	07SEP2020	9.0	5.0	Normal	Normal
06/0611		ES	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
		ES	VISIT 1	14JUL2015	37.0	3.0	Normal	Normal
06/0612	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	14JUL2015	33.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	19OCT2015	40.0	1.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	25NOV2015	41.0	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	11JAN2016	27.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	11APR2016	31.0	2.8	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	19MAY2016	36.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	26OCT2016	27.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	19OCT2017	28.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	28NOV2019	21.0	2.8	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	14OCT2020	14.0	3.4	Normal	Normal
06/0613	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	17JUL2015	3.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 4	04SEP2015	6.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	16OCT2015	0.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 6	15JAN2016	0.0	4.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 7	15JUL2016	0.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	09AUG2017	0.0	4.0	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
06/0613	SC	ES/SAF/FAS	VISIT 11	11AUG2020	0.0	3.0	Normal	Normal
06/0614	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	UNSCHEDULED	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	14AUG2015	41.0	3.5	Normal	Abnormal / sacroiliac joint right
	ND plus	ES/SAF/FAS	VISIT 3A	16NOV2015	35.0	4.0	Normal	Abnormal / Facette L5/S1 on both sides of
	ND plus	ES/SAF/FAS	VISIT 4	04JAN2016	31.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	09FEB2016	45.0	3.7	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	22FEB2016	45.0	3.7	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	10MAR2016	39.0	3.5	Normal	Abnormal / L5/S1
	ND plus	ES/SAF/FAS	VISIT 6	02MAY2016	33.5	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	03AUG2016	37.0	4.0	Normal	Abnormal / L5/S1
	ND plus	ES/SAF/FAS	VISIT 7	17NOV2016	43.5	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	02NOV2017	36.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	15NOV2017	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 11	10DEC2020	28.0	3.0	Normal	Normal
06/0615	ND basic	ES/SAF	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF	VISIT 1	21AUG2015	24.0	2.0	Normal	Normal
06/0616		ES	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
		ES	VISIT 1	05NOV2015	12.0	5.0	Normal	Abnormal / lumbar syndrom
06/0617	ND plus	ES/SAF	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF	VISIT 1	21DEC2015	32.0	4.5	Normal	Abnormal / ISG right
	ND plus	ES/SAF	VISIT 3A	08MAR2016	34.0	4.2	Normal	Normal
06/0618		ES	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
		ES	VISIT 1	14JAN2016	36.0	2.2	Normal	Normal
06/0619	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 1	22FEB2016	40.0	4.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 3A	09MAY2016	12.5	5.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	20JUN2016	24.5	6.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	04AUG2016	14.0	5.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	03NOV2016	18.0	6.2	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 7	15MAY2017	23.0	5.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	02MAY2018	28.5	4.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	28MAY2021	30.5	4.5	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
06/0620	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	23FEB2016	57.0	3.0	Normal	Abnormal / ISG left
	SC	ES/SAF/FAS	VISIT 4	12APR2016	38.0	2.8	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	23MAY2016	40.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 6	17AUG2016	33.0	4.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 7	20FEB2017	24.0	5.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	26MAR2018	29.5	6.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 11	02MAR2021	27.0	5.5	Normal	Normal
07/0701	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	04NOV2014	50.0	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	19JAN2015	4.0	6.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	04MAR2015	5.0	6.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	27APR2015	10.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	20JUL2015	15.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	14JAN2016	0.0	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	30JAN2017	5.0	Not done	Normal	Normal
07/0702	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	19JAN2015	40.0	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 4	02MAR2015	25.0	2.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	20APR2015	25.0	2.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 6	21JUL2015	20.0	3.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	14FEB2018	25.0	Not done	Normal	Normal
07/0703	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	27FEB2015	Not done	Not done	Not done	Abnormal / ISG Pain bds.
	ND plus	ES/SAF/FAS	VISIT 3A	18MAY2015	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	29JUN2015	15.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	17AUG2015	15.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	09NOV2015	16.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	09MAY2016	16.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	24APR2017	10.0	4.0	Normal	Normal
07/0704	ND plus	ES/SAF/FAS	VISIT 11	20JUL2020	10.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 1	14JUL2015	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 3A	06OCT2015	0.0	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	16NOV2015	0.0	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	11JAN2016	0.0	Not done	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
07/0704	ND basic	ES/SAF/FAS	VISIT 6	11APR2016	1.0	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 7	21NOV2016	1.0	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	02OCT2017	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	21SEP2020	13.0	5.0	Normal	Normal
07/0705		ES	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
		ES	VISIT 1	11AUG2015	20.0	1.0	Normal	Abnormal / pressure pain
07/0706	SC	ES/SAF/FAS	VISIT 1	30NOV2015	15.0	3.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 4	12JAN2016	Not done	Not done	Abnormal / today acute low back pain left	Abnormal / today acute low back pain left
07/0707		ES	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
		ES	VISIT 1	18FEB2016	Not done	Not done	Not done	Not done
08/0801	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	31OCT2014	15.0	Not done	Abnormal / right single support	Abnormal / SIJ, low lumbar
	SC	ES/SAF/FAS	VISIT 4	22DEC2014	45.0	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	12FEB2015	20.0	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 6	04MAY2015	20.0	Not done	Normal	Abnormal / Paramedian both sides in wound area
08/0802	ND plus	ES/SAF/FAS	VISIT 1	26NOV2014	5.0	2.0	Normal	Abnormal / paraverebral, right
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	26NOV2014	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 3A	03MAR2015	4.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	08APR2015	0.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	01JUN2015	0.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	17AUG2015	0.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	22FEB2016	1.0	9.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	02FEB2017	1.0	7.0	Normal	Abnormal / Pressure pain sacroiliac joint left
	ND plus	ES/SAF/FAS	UNSCHEDULED	13MAR2017	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 11	19MAR2020	0.0	7.0	Normal	Normal
08/0803	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 1	24FEB2015	15.0	5.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 3A	15JUN2015	15.0	6.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	24JUL2015	9.0	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	07SEP2015	7.0	Not done	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
08/0804	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	02JUN2015	13.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	20AUG2015	15.0	9.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	28SEP2015	35.0	9.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	13NOV2015	28.0	6.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	05FEB2016	30.0	6.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	22AUG2016	13.0	7.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	04AUG2017	45.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	04AUG2020	40.0	6.0	Normal	Normal
08/0805	ND basic	ES/SAF/FAS	VISIT 1	19JUN2015	10.0	Not done	Normal	Abnormal / Left iliosacral joint pain Facett joint pain right+left.
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	24JUN2015	9.0	3.0	Normal	Abnormal / ISJ-pain left, facett joint pain right+left L2/3, L3/4
	ND basic	ES/SAF/FAS	VISIT 3A	21SEP2015	1.0	7.0	Normal	Abnormal / pain on percussion/pressure ISG (l)>(re)
	ND basic	ES/SAF/FAS	VISIT 4	02NOV2015	0.0	6.0	Normal	Abnormal / Pressure pain L 2/3, 3/4 left, L 4/5 right
	ND basic	ES/SAF/FAS	VISIT 5	21DEC2015	1.0	7.0	Normal	Abnormal / Pressure pain L3/4, 4/5 left, L5/S1 right, ISJ right
	ND basic	ES/SAF/FAS	VISIT 6	07MAR2016	0.0	9.0	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	24JUN2016	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	28JUL2016	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 7	14FEB2017	3.0	8.0	Normal	Abnormal / paravertebral mild Right = Left
	ND basic	ES/SAF/FAS	VISIT 8	28AUG2017	0.0	7.0	Normal	Abnormal / Facet joint pain L4/5 left and SI-joint pressure pain on both sides. Pain on percussion above L4, L5, sacral
	ND basic	ES/SAF/FAS	VISIT 11	03SEP2020	1.0	7.0	Normal	Normal
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	07JUL2015	9.0	1.0	Normal	Normal
08/0806	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	07JUL2015	9.0	1.0	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
08/0806	ND plus	ES/SAF/FAS	VISIT 3A	28SEP2015	25.0	8.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	06NOV2015	25.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	23DEC2015	25.0	6.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	14MAR2016	35.0	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	27SEP2016	10.0	7.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	12OCT2017	26.0	5.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	24SEP2020	10.0	7.0	Normal	Normal
08/0807	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	18NOV2015	13.0	5.0	Normal	Abnormal / Pain on facette joint L4/5 right and ISJ
	ND plus	ES/SAF/FAS	VISIT 3A	01FEB2016	25.0	6.0	Normal	Abnormal / paravertebral L4 (re)
	ND plus	ES/SAF/FAS	VISIT 4	08MAR2016	23.0	4.0	Normal	Abnormal / percussion pain, paravertebral ri + le, ISJ le + ri
	ND plus	ES/SAF/FAS	UNSCHEDULED	16MAR2016	Not done	Not done	Normal	Abnormal / ISJ pain right + left
	ND plus	ES/SAF/FAS	VISIT 5	03MAY2016	10.0	9.0	Normal	Abnormal / percussion pain, paravertebral left/ISG
	ND plus	ES/SAF/FAS	VISIT 6	28JUL2016	2.0	6.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	06FEB2017	6.0	6.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	19FEB2018	11.0	4.0	Normal	Abnormal / pressure pain ISG (L)
08/0808	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 11	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	02DEC2015	0.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 4	07JAN2016	1.5	7.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	26FEB2016	0.0	8.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 6	03JUN2016	0.0	9.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 7	28NOV2016	0.0	7.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	13NOV2017	0.0	7.0	Normal	Normal
09/0901	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	27OCT2014	15.0	2.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 4	08DEC2014	29.0	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	27JAN2015	16.0	2.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 6	05MAY2015	15.0	5.0	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
09/0901	SC	ES/SAF/FAS	VISIT 7	03NOV2015	13.0	3.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	22NOV2016	9.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 11	28OCT2019	12.0	4.0	Normal	Normal
09/0902		ES	VISIT 1	12NOV2014	55.0	2.0	Normal	Normal
09/0903	ND plus	ES/SAF	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF	VISIT 1	19NOV2014	22.0	2.5	Normal	Normal
	ND plus	ES/SAF	VISIT 3A	11FEB2015	37.0	3.0	Normal	Normal
09/0904	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 1	05FEB2015	Not done	Not done	Abnormal / sciatic malposition	Abnormal / lumbar spine
	ND basic	ES/SAF/FAS	VISIT 3A	20MAY2015	20.0	2.5	Normal	Abnormal / pressure pain surgical site
	ND basic	ES/SAF/FAS	VISIT 4	08JUL2015	12.0	3.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	26AUG2015	20.0	2.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	17NOV2015	18.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 7	23MAY2016	9.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	24APR2017	10.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	11MAY2020	5.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	11MAY2020	5.0	4.0	Normal	Normal
09/0905	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	18MAR2015	55.0	1.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	24JUN2015	17.0	2.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	10AUG2015	20.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	28SEP2015	5.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	21DEC2015	0.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	20JUN2016	0.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	19JUN2017	7.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	26SEP2018	50.0	1.0	Abnormal / bowed posture	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	20FEB2019	40.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	25MAY2020	10.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	25MAY2020	10.0	4.0	Normal	Normal
09/0906		ES	VISIT 1	26MAR2015	3.5	4.5	Not done	Not done
09/0907	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	13APR2015	23.0	3.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 4	26MAY2015	15.0	2.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	14JUL2015	14.0	3.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 6	09NOV2015	10.0	3.0	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
09/0907	SC	ES/SAF/FAS	VISIT 7	04APR2016	8.0	3.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	10APR2017	7.0	3.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 11	12MAY2020	20.0	3.0	Normal	Normal
09/0908	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 1	05MAY2015	65.0	1.0	Abnormal / sciatic malposition	Normal
	ND basic	ES/SAF/FAS	VISIT 3A	05AUG2015	43.0	2.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	21SEP2015	38.0	2.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	02NOV2015	28.0	3.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	25JAN2016	30.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 7	20JUL2016	14.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	17JUL2017	28.0	3.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	22JUN2020	32.0	3.5	Normal	Normal
09/0909	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	11MAY2015	Not done	Not done	Abnormal / sciatic malposition	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	12AUG2015	0.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	20AUG2015	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	28SEP2015	0.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	09NOV2015	0.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	01FEB2016	0.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	18JUL2016	0.0	4.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	24JUL2017	0.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	27JUL2020	0.0	5.0	Normal	Normal
09/0910	ND plus	ES/SAF	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF	VISIT 1	31AUG2015	Not done	Not done	Not done	Not done
09/0911	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	15OCT2015	0.0	7.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	13JAN2016	0.0	4.5	Normal	Abnormal / Pressure pain
	ND plus	ES/SAF/FAS	VISIT 4	22FEB2016	1.5	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	11APR2016	0.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	04JUL2016	0.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	16JAN2017	0.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	29JAN2018	2.0	6.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	18JAN2021	3.0	4.0	Normal	Normal
09/0912	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
09/0912	ND plus	ES/SAF/FAS	VISIT 1	19OCT2015	55.0	1.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	20JAN2016	25.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	29FEB2016	27.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	25APR2016	25.0	3.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	25JUL2016	20.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	23JAN2017	24.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	15JAN2018	30.0	4.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	25JAN2021	20.0	3.5	Normal	Normal
09/0913	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 1	26NOV2015	50.0	2.5	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	03DEC2015	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 3A	17FEB2016	20.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	04APR2016	19.0	2.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	23MAY2016	10.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	01AUG2016	7.0	6.0	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	25JAN2017	25.0	3.0	Normal	Abnormal / moderate pressure pain directly below operation scar.
	ND basic	ES/SAF/FAS	VISIT 7	30JAN2017	5.0	3.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	05FEB2018	0.0	5.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	08MAR2021	10.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	04JAN2016	33.0	3.0	Abnormal / Stooped relieving posture	Abnormal / Pressure pain
	SC	ES/SAF/FAS	VISIT 4	15FEB2016	38.0	3.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	11APR2016	28.0	4.5	Normal	Normal
09/0914	SC	ES/SAF/FAS	VISIT 6	27JUN2016	29.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 7	09JAN2017	30.0	3.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	08JAN2018	39.0	3.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 11	11JAN2021	12.0	5.5	Normal	Normal
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 1	05JAN2016	35.0	3.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 3A	23MAR2016	20.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	02MAY2016	10.0	5.0	Normal	Normal
09/0915	ND basic	ES/SAF/FAS	VISIT 5	20JUN2016	0.0	5.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	26SEP2016	3.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	21DEC2016	Not done	Not done	Normal	Abnormal / low back pressure pain

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
09/0915	ND basic	ES/SAF/FAS	VISIT 7	03APR2017	0.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	09APR2018	0.0	4.5	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	23JUL2020	0.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	22FEB2021	0.0	4.0	Normal	Normal
09/0916	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	22FEB2016	58.0	1.0	Abnormal / claudication right leg	Abnormal / lumbar pain
	SC	ES/SAF/FAS	VISIT 4	06APR2016	48.0	2.5	Normal	Abnormal / Surgical site
	SC	ES/SAF/FAS	VISIT 5	30MAY2016	35.0	3.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 6	29AUG2016	30.0	4.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 7	20FEB2017	27.0	4.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	26FEB2018	35.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 11	01MAR2021	38.0	3.5	Normal	Normal
10/1001		ES	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
		ES	VISIT 1	30NOV2015	0.0	Not done	Normal	Normal
11/1101	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	12JAN2015	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	30MAR2015	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	11MAY2015	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	03JUL2015	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	09OCT2015	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	08APR2016	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	24JAN2017	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	27SEP2017	Not done	Not done	Abnormal / gait an posture primarily perform by right leg; patient trying to avoid pressure to left ankle + foot	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	28JUN2019	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	30JUL2019	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	21APR2020	Not done	Not done	Normal	Abnormal / Low back pain
11/1102	ND basic	ES/SAF/FAS	VISIT 1	15APR2015	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	20APR2015	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 3A	27JUL2015	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	11SEP2015	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 5	23OCT2015	Not done	Not done	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
11/1102	ND basic	ES/SAF/FAS	VISIT 6	05FEB2016	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 7	29JUL2016	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	14JUL2017	Not done	Not done	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	18AUG2020	Not done	Not done	Normal	Normal
11/1103	SC	ES/SAF/FAS	VISIT 1	30JUL2015	Not done	Not done	Abnormal / pain-induced dragging left leg	Abnormal / lower back
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	03AUG2015	Not done	Not done	Abnormal / s. screening	Abnormal / s. screening
	SC	ES/SAF/FAS	VISIT 4	18SEP2015	Not done	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	06NOV2015	Not done	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 6	12FEB2016	Not done	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 7	05AUG2016	Not done	Not done	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	04AUG2017	Not done	Not done	Normal	Normal
	SC	ES/SAF/FAS	UNSCHEDULED	05JAN2018	Not done	Not done	Abnormal / Pain-related reduced	Abnormal / Back pain
	SC	ES/SAF/FAS	UNSCHEDULED	14FEB2018	Not done	Not done	Normal	Normal
11/1104	SC	ES/SAF/FAS	VISIT 11	25AUG2020	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 1	01MAR2016	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	07MAR2016	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	06JUN2016	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	22JUL2016	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	09SEP2016	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	25NOV2016	Not done	Not done	Abnormal / lunge right side	Normal
	ND plus	ES/SAF/FAS	VISIT 7	30MAY2017	Not done	Not done	Abnormal / lunge right sided	Normal
	ND plus	ES/SAF/FAS	VISIT 8	12JUN2018	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	28MAY2021	Not done	Not done	Normal	Normal
12/1201	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	UNSCHEDULED	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	04SEP2015	Not done	Not done	Abnormal / Antalgie	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	22OCT2015	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 3A	30NOV2015	Not done	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	08JAN2016	10.0	Not done	Normal	Abnormal / pain left SIJ
	ND plus	ES/SAF/FAS	VISIT 5	26FEB2016	3.0	Not done	Normal	Abnormal / paravertebral left very slightly
	ND plus	ES/SAF/FAS	VISIT 6	18MAY2016	17.0	Not done	Abnormal / claudication	Abnormal / paravertebral pressure pain both sides lumbar

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
12/1201	ND plus	ES/SAF/FAS	UNSCHEDULED	03AUG2016	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 7	22NOV2016	10.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	19JUL2017	15.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	21NOV2017	10.0	Not done	Normal	Normal
	ND plus	ES/SAF/FAS	UNSCHEDULED	27JUN2018	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 11	01DEC2020	5.0	Not done	Normal	Abnormal / Facett joint pain at OP level
12/1202		ES	VISIT 1	-	Not done	Not done	Not done	Not done
13/1301	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	UNSCHEDULED	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	UNSCHEDULED	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	23APR2015	50.0	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	28JUL2015	24.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	08SEP2015	26.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	22OCT2015	11.0	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	11JAN2016	14.0	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	20JUL2016	2.5	4.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	28JUN2017	0.0	5.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	24JUN2020	0.0	4.5	Normal	Normal
13/1302	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF/FAS	VISIT 1	11MAY2015	44.0	2.0	Abnormal / Stooped gait	Normal
	ND plus	ES/SAF/FAS	VISIT 3A	28JUL2015	30.5	2.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 4	08SEP2015	19.5	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 5	22OCT2015	13.0	3.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 6	11JAN2016	13.5	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 7	19JUL2016	9.0	4.5	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 8	19JUL2017	6.5	4.0	Normal	Normal
	ND plus	ES/SAF/FAS	VISIT 11	01JUL2020	10.0	Not done	Normal	Normal
13/1303	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	SC	ES/SAF/FAS	VISIT 1	25JUN2015	28.5	0.9	Abnormal / limping, right	Normal
	SC	ES/SAF/FAS	VISIT 4	01SEP2015	15.0	1.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 5	29SEP2015	0.0	3.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 6	14DEC2015	0.0	5.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 7	06JUL2016	0.0	4.0	Normal	Normal
	SC	ES/SAF/FAS	VISIT 8	12JUL2017	0.0	7.0	Normal	Normal
	SC	ES/SAF/FAS	UNSCHEDULED	20DEC2017	32.5	3.5	Normal	Normal
	SC	ES/SAF/FAS	VISIT 11	03JUN2020	30.5	3.5	Normal	Normal

Listing 16.2.2.4: Functional Status - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Finger-ground distance (cm)	Schober's sign (cm)	Posture and gait	Percussion tenderness/ pressure pain
13/1303	SC	ES/SAF/FAS	UNSCHEDULED	17JUN2020	95.0	3.5	Normal	Abnormal / backward thigh muscles
13/1304	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 1	28JUN2015	52.5	1.5	Abnormal / hollow back, unstableness	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	18AUG2015	0.0	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 3A	15SEP2015	25.0	2.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 4	02NOV2015	23.5	3.5	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	17NOV2015	Not done	Not done	Not done	Not done
	ND basic	ES/SAF/FAS	VISIT 5	14DEC2015	17.5	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 6	01APR2016	18.0	3.0	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	27JUL2016	23.0	3.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 7	14SEP2016	18.5	4.0	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 8	06SEP2017	0.0	5.2	Normal	Normal
	ND basic	ES/SAF/FAS	UNSCHEDULED	30MAY2018	0.0	4.5	Normal	Normal
	ND basic	ES/SAF/FAS	VISIT 11	02SEP2020	0.0	4.0	Normal	Normal
13/1305	ND plus	ES/SAF	BASELINE (VISIT 2A)	-	Not done	Not done	Not done	Not done
	ND plus	ES/SAF	VISIT 1	13OCT2015	38.0	2.5	Abnormal / uncertenty, slow	Abnormal / pain on palpation on spine

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	45.18
				Reported Health Transition	1.00
				Physical Functioning Score	29.88
				Role/Physical Score	56.24
				Role Emotional Score	34.27
				Social Functioning Score	35.42
				Bodily Pain Score	25.07
				Mental Health Score	39.08
				Vitality Score	39.59
				Physical Component Summary	37.32
				Mental Component Summary	35.75
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score Reported Health Transition	51.56

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 3 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	34.07
				Role/Physical Score	49.17
				Role Emotional Score	44.81
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	45.90
				Vitality Score	49.05
				Physical Component Summary	38.85
				Mental Component Summary	45.91
				In general, would you say your health is:	
				Compared to one year ago, how would you rate your health in general now?	
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 4 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 5 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	45.18
				Reported Health Transition	3.00
				Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	29.35

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 6 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	41.36
				Vitality Score	41.95
				Physical Component Summary	36.83
				Mental Component Summary	46.15
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 7 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 8 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	42.63
				Reported Health Transition	4.00
				Physical Functioning Score	27.78
				Role/Physical Score	42.10
				Role Emotional Score	44.81
				Social Functioning Score	40.85
				Bodily Pain Score	29.35
				Mental Health Score	30.00
				Vitality Score	41.95

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 9 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	32.20
				Mental Component Summary	39.77
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 10 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 11 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	37.21
				Reported Health Transition	4.00
				Physical Functioning Score	31.97
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	30.00
				Bodily Pain Score	29.35
				Mental Health Score	36.81
				Vitality Score	41.95
				Physical Component Summary	34.14
				Mental Component Summary	42.11

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 12 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 13 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 14 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	41.04
				Reported Health Transition	3.00
				Physical Functioning Score	38.27
				Role/Physical Score	49.17
				Role Emotional Score	55.34
				Social Functioning Score	30.00
				Bodily Pain Score	37.48
				Mental Health Score	18.64
				Vitality Score	34.85
				Physical Component Summary	41.67
				Mental Component Summary	30.18
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 15 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 16 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 17 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 8	Global Health Score	35.62
				Reported Health Transition	3.00
				Physical Functioning Score	31.97
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	24.57
				Bodily Pain Score	29.35
				Mental Health Score	18.64
				Vitality Score	25.39
				Physical Component Summary	37.32
				Mental Component Summary	27.95
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 18 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 19 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 20 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
			Visit 9	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
				Global Health Score	34.02
				Reported Health Transition	2.00
				Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	29.35
				Mental Health Score	14.09
				Vitality Score	27.75
				Physical Component Summary	41.47
				Mental Component Summary	27.31
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 21 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 22 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 23 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 10	Global Health Score	42.00
				Reported Health Transition	3.00
				Physical Functioning Score	34.07
				Role/Physical Score	49.17
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	33.63
				Mental Health Score	27.73
				Vitality Score	41.95
				Physical Component Summary	37.03
				Mental Component Summary	40.51
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 24 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 25 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 26 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 11	Global Health Score	37.21
				Reported Health Transition	3.00
				Physical Functioning Score	36.17
				Role/Physical Score	27.95
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	33.63
				Mental Health Score	30.00
				Vitality Score	34.85
				Physical Component Summary	28.61
				Mental Component Summary	40.70
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 27 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 28 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 29 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	49.01
				Reported Health Transition	1.00
				Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	33.63
				Mental Health Score	45.90
				Vitality Score	37.22
				Physical Component Summary	47.63
				Mental Component Summary	31.12
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 31 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 32 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	51.56
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 33 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	53.79
				Physical Component Summary	51.26
				Mental Component Summary	41.53
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 34 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 35 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	54.75
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	62.75

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 36 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	50.44
				Vitality Score	51.42
				Physical Component Summary	52.99
				Mental Component Summary	38.71
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 38 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 5	Global Health Score	56.35
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	39.59

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 39 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	53.05
				Mental Component Summary	35.90
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 40 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 41 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	44.56
				Role/Physical Score	49.17
				Role Emotional Score	55.34
				Social Functioning Score	57.14
				Bodily Pain Score	37.48
				Mental Health Score	52.72
				Vitality Score	39.59
				Physical Component Summary	39.14
				Mental Component Summary	53.55

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 42 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 43 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 44 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	49.01
				Reported Health Transition	1.00
				Physical Functioning Score	50.85
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	45.90
				Vitality Score	49.05
				Physical Component Summary	47.14
				Mental Component Summary	38.20
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 45 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 46 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 47 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	49.97
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	53.79
				Physical Component Summary	50.86
				Mental Component Summary	41.55
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 48 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 49 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 50 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	56.35
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	53.79
				Physical Component Summary	50.28
				Mental Component Summary	42.12
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 51 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 52 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 53 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 10	Global Health Score	56.35
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	65.62
				Physical Component Summary	52.80
				Mental Component Summary	44.24
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 54 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 55 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 56 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 11	Global Health Score	57.94
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	58.52
				Physical Component Summary	52.49
				Mental Component Summary	43.64
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 57 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 58 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 59 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	53.79
				Reported Health Transition	2.00
				Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	57.14
				Bodily Pain Score	37.48
				Mental Health Score	48.17
				Vitality Score	53.79
				Physical Component Summary	42.05
				Mental Component Summary	54.73
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 61 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 62 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	49.01
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 63 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	37.48
				Mental Health Score	52.72
				Vitality Score	60.89
				Physical Component Summary	44.35
				Mental Component Summary	45.93
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 64 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 65 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 4	Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	48.75
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 66 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	50.44
				Vitality Score	53.79
				Physical Component Summary	48.67
				Mental Component Summary	41.08
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 67 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 68 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	48.75
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	42.19
				Mental Health Score	52.72
				Vitality Score	56.15

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 69 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	49.76
				Mental Component Summary	42.26
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 70 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 71 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	45.84
				Mental Component Summary	43.47

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 72 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 73 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 74 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	53.79
				Reported Health Transition	4.00
				Physical Functioning Score	46.66
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	37.48
				Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	47.24
				Mental Component Summary	42.08
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 75 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 76 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 77 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	53.79
				Reported Health Transition	2.00
				Physical Functioning Score	48.75
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	41.77
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	42.17
				Mental Component Summary	44.92
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 78 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 79 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 80 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	44.23
				Reported Health Transition	2.00
				Physical Functioning Score	43.16
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	36.81
				Vitality Score	46.69
				Physical Component Summary	43.28
				Mental Component Summary	42.67
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 81 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 82 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 83 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 10	Global Health Score	39.44
				Reported Health Transition	2.00
				Physical Functioning Score	44.56
				Role/Physical Score	35.03
				Role Emotional Score	34.27
				Social Functioning Score	51.71
				Bodily Pain Score	46.48
				Mental Health Score	43.63
				Vitality Score	53.79
				Physical Component Summary	40.74
				Mental Component Summary	42.92
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 84 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 85 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 86 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 11	Global Health Score	42.63
				Reported Health Transition	3.00
				Physical Functioning Score	46.66
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	50.44
				Vitality Score	56.15
				Physical Component Summary	40.49
				Mental Component Summary	44.01
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 87 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 88 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 89 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	43.59
				Reported Health Transition	1.00
				Physical Functioning Score	19.39
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	19.93
				Mental Health Score	23.18
				Vitality Score	27.75
				Physical Component Summary	29.93
				Mental Component Summary	38.78
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 91 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 92 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	50.61
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 93 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	48.75
				Role/Physical Score	49.17
				Role Emotional Score	55.34
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	34.54
				Vitality Score	46.69
				Physical Component Summary	49.66
				Mental Component Summary	42.59
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 94 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 95 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 4	Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 96 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	43.63
				Vitality Score	46.69
				Physical Component Summary	48.01
				Mental Component Summary	36.40
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 97 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 98 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	43.63
				Vitality Score	46.69

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 99 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	50.10
				Mental Component Summary	35.84
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 100 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 101 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	43.63
				Vitality Score	46.69
				Physical Component Summary	55.32
				Mental Component Summary	34.23

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 102 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 103 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 104 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 7	Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	62.75
				Mental Health Score	43.63
				Vitality Score	53.79
				Physical Component Summary	55.56
				Mental Component Summary	34.44
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 105 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 106 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 107 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	52.20
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	41.36
				Vitality Score	51.42
				Physical Component Summary	49.94
				Mental Component Summary	35.90
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 109 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 110 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 9	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	43.63
				Vitality Score	46.69
				Physical Component Summary	49.70
				Mental Component Summary	35.87
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 112 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 113 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	52.20
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	41.36
				Vitality Score	56.15
				Physical Component Summary	50.07
				Mental Component Summary	37.02
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 114 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 115 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 116 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 11	Global Health Score	58.58
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	39.08
				Vitality Score	49.05
				Physical Component Summary	52.85
				Mental Component Summary	33.66
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 117 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 118 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 119 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	47.42
				Reported Health Transition	3.00
				Physical Functioning Score	40.36
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	30.00
				Bodily Pain Score	29.35
				Mental Health Score	23.18
				Vitality Score	32.49
				Physical Component Summary	41.60
				Mental Component Summary	20.07
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 121 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 122 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	42.63
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 123 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	48.75
				Role/Physical Score	35.03
				Role Emotional Score	34.27
				Social Functioning Score	46.28
				Bodily Pain Score	51.61
				Mental Health Score	27.73
				Vitality Score	37.22
				Physical Component Summary	48.02
				Mental Component Summary	28.32
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 124 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 125 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 4	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	34.27
			Visit 4	Social Functioning Score	51.71
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 126 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	36.81
				Vitality Score	39.59
				Physical Component Summary	47.33
				Mental Component Summary	34.53
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 127 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 128 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 5	Global Health Score	44.23
				Reported Health Transition	2.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	32.27
				Vitality Score	41.95

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 129 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	48.79
				Mental Component Summary	29.87
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 130 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 131 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	42.63
				Reported Health Transition	2.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	34.27
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	41.36
				Vitality Score	39.59
				Physical Component Summary	43.64
				Mental Component Summary	35.42

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 132 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 133 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 134 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	41.04
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	34.27
				Social Functioning Score	57.14
				Bodily Pain Score	41.77
				Mental Health Score	34.54
				Vitality Score	41.95
				Physical Component Summary	42.34
				Mental Component Summary	36.55
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 135 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 136 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 137 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
			Visit 8	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	47.42
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	41.36
				Vitality Score	41.95
				Physical Component Summary	52.01
				Mental Component Summary	32.67
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 139 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 140 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 9	Global Health Score	44.23
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	55.90
				Mental Health Score	36.81
				Vitality Score	39.59
				Physical Component Summary	50.01
				Mental Component Summary	29.16
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 142 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 143 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 10	Global Health Score	47.42
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	51.61
				Mental Health Score	32.27
				Vitality Score	34.85
				Physical Component Summary	44.33
				Mental Component Summary	37.01
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 144 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 145 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 146 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	41.36
				Vitality Score	41.95
				Physical Component Summary	50.63
				Mental Component Summary	33.28
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 147 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 148 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 149 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	45.82
				Reported Health Transition	1.00
				Physical Functioning Score	25.68
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	29.35
				Mental Health Score	30.00
				Vitality Score	32.49
				Physical Component Summary	34.81
				Mental Component Summary	39.34
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	
				Does your health now limit you in these activities? If so, how much? Walking one block	

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 151 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 152 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	55.39
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 153 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	44.56
				Role/Physical Score	42.10
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	51.61
				Mental Health Score	45.90
				Vitality Score	46.69
				Physical Component Summary	44.17
				Mental Component Summary	46.96
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 154 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 155 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	46.66
				Role/Physical Score	49.17
				Role Emotional Score	34.27
			Visit 4	Social Functioning Score	51.71
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 156 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	41.36
				Vitality Score	46.69
				Physical Component Summary	51.31
				Mental Component Summary	37.24
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 157 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 158 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	57.94
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	54.18
				Mental Health Score	59.53
				Vitality Score	56.15

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 159 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	49.20
				Mental Component Summary	45.02
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 160 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 161 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	51.66
				Mental Component Summary	41.37

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 162 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 163 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 164 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	47.73
				Mental Component Summary	41.83
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 165 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 166 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 167 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 8	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	45.31
				Mental Component Summary	42.38
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 168 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 169 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 170 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	47.42
				Reported Health Transition	2.00
				Physical Functioning Score	40.36
				Role/Physical Score	49.17
				Role Emotional Score	44.81
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	43.63
				Vitality Score	44.32
				Physical Component Summary	40.85
				Mental Component Summary	42.32
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 171 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 172 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 173 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 10	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	45.90
				Vitality Score	51.42
				Physical Component Summary	48.19
				Mental Component Summary	38.13
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 174 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 175 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 176 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	56.98
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	46.10
				Mental Component Summary	42.33
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 177 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 178 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 179 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	53.16
				Reported Health Transition	1.00
				Physical Functioning Score	21.49
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	30.00
				Bodily Pain Score	29.35
				Mental Health Score	32.27
				Vitality Score	27.75
				Physical Component Summary	34.27
				Mental Component Summary	38.72
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 181 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 182 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	56.98
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 183 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	46.66
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	51.61
				Mental Health Score	52.72
				Vitality Score	53.79
				Physical Component Summary	55.15
				Mental Component Summary	37.43
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 184 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 185 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	48.75
				Role/Physical Score	49.17
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	46.28
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 186 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	59.53
				Vitality Score	60.89
				Physical Component Summary	52.26
				Mental Component Summary	42.80
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 188 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	59.53
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	59.53
				Vitality Score	60.89

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 189 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	48.92
				Mental Component Summary	46.36
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 190 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 191 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	59.53
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	54.13
				Mental Component Summary	40.65

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 192 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 193 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 194 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 7	Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	65.62
				Physical Component Summary	52.35
				Mental Component Summary	46.41
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 195 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 196 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 197 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	57.94
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	56.15
				Physical Component Summary	53.93
				Mental Component Summary	39.78
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 198 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 199 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 200 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
			Visit 9	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	65.62
				Physical Component Summary	52.59
				Mental Component Summary	46.39
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 202 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 203 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 10	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	60.89
				Physical Component Summary	52.45
				Mental Component Summary	45.28
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 204 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 205 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 206 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 11	Global Health Score	59.53
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	60.89
				Physical Component Summary	52.45
				Mental Component Summary	45.28
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 207 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 208 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 209 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0112	NDisc basic	ES/SAF	Baseline (Visit 2a)	Global Health Score	45.82
				Reported Health Transition	1.00
				Physical Functioning Score	42.46
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	29.35
				Mental Health Score	45.90
				Vitality Score	41.95
				Physical Component Summary	39.79
				Mental Component Summary	33.46
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 211 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0112	NDisc basic	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 212 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0112	NDisc basic	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 213 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	51.56
				Reported Health Transition	2.00
				Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	33.63
				Mental Health Score	54.99
				Vitality Score	53.79
				Physical Component Summary	43.18
				Mental Component Summary	41.32
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 214 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 215 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	56.98
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 216 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	44.56
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	54.18
				Mental Health Score	54.99
				Vitality Score	58.52
				Physical Component Summary	52.19
				Mental Component Summary	42.21
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 217 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 218 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	56.35
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 219 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	59.53
				Vitality Score	65.62
				Physical Component Summary	50.02
				Mental Component Summary	47.41
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 221 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 5	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	59.53
				Vitality Score	65.62

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 222 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	49.52
				Mental Component Summary	47.54
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 223 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 224 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	65.62
				Physical Component Summary	52.59
				Mental Component Summary	46.39

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 225 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 226 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 227 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 7	Global Health Score	57.94
				Reported Health Transition	2.00
				Physical Functioning Score	36.17
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	37.48
				Mental Health Score	59.53
				Vitality Score	60.89
				Physical Component Summary	40.11
				Mental Component Summary	50.84
				In general, would you say your health is:	Excellent

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 228 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 229 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 230 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	59.53
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	65.62
				Physical Component Summary	52.59
				Mental Component Summary	46.39
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 231 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 232 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 233 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 9	Global Health Score	56.98
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	65.62
				Physical Component Summary	51.06
				Mental Component Summary	46.92
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 235 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 236 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	58.58
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	65.62
				Physical Component Summary	51.46
				Mental Component Summary	46.89
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 237 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 238 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 239 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 11	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	65.62
				Physical Component Summary	52.59
				Mental Component Summary	46.39
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 240 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 241 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 242 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	47.42
				Reported Health Transition	1.00
				Physical Functioning Score	17.29
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	24.21
				Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	31.50
				Mental Component Summary	47.90
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 244 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 245 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	50.61
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 246 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	50.85
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	42.19
				Mental Health Score	48.17
				Vitality Score	46.69
				Physical Component Summary	45.69
				Mental Component Summary	36.22
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 247 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 248 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	62.75

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 249 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	52.72
				Vitality Score	53.79
				Physical Component Summary	52.63
				Mental Component Summary	40.79
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 250 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 251 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 5	Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	56.15

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 252 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	52.69
				Mental Component Summary	41.35
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 253 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 254 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	53.58
				Mental Component Summary	40.87

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 255 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 256 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 257 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 7	Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	46.69
				Physical Component Summary	52.81
				Mental Component Summary	39.74
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 258 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 259 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 260 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 8	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	58.52
				Physical Component Summary	53.89
				Mental Component Summary	41.41
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 261 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 262 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 263 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 9	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	52.39
				Mental Component Summary	40.94
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 265 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 266 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 10	Global Health Score	56.35
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	60.89
				Physical Component Summary	52.66
				Mental Component Summary	43.12
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 267 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 268 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 269 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 11	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	58.52
				Physical Component Summary	54.39
				Mental Component Summary	40.31
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 270 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 271 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 272 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	53.79
				Reported Health Transition	2.00
				Physical Functioning Score	36.17
				Role/Physical Score	49.17
				Role Emotional Score	44.81
				Social Functioning Score	40.85
				Bodily Pain Score	33.20
				Mental Health Score	30.00
				Vitality Score	32.49
				Physical Component Summary	41.97
				Mental Component Summary	34.19
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 274 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 275 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	53.79
				Reported Health Transition	4.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 276 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	42.46
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	36.81
				Vitality Score	39.59
				Physical Component Summary	54.05
				Mental Component Summary	27.87
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 277 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 278 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	48.75
				Role/Physical Score	49.17
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	40.85
				Bodily Pain Score	42.19

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 279 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	41.36
				Vitality Score	49.05
				Physical Component Summary	51.78
				Mental Component Summary	30.72
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 280 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 281 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	45.82
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	37.48
				Mental Health Score	41.36
				Vitality Score	51.42

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 282 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	49.61
				Mental Component Summary	32.81
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 283 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 284 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	50.44
				Vitality Score	51.42
				Physical Component Summary	48.78
				Mental Component Summary	39.95

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 285 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 286 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 287 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 7	Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	50.44
				Vitality Score	53.79
				Physical Component Summary	48.40
				Mental Component Summary	40.85
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 288 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 289 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 290 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 8	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	55.90
				Mental Health Score	43.63
				Vitality Score	53.79
				Physical Component Summary	51.70
				Mental Component Summary	35.64
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 291 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 292 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 293 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
			Visit 9	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	56.98
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	48.17
				Vitality Score	53.79
				Physical Component Summary	53.23
				Mental Component Summary	38.61
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 294 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 295 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 296 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	56.98
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	53.79
				Physical Component Summary	52.77
				Mental Component Summary	38.26
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 297 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 298 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 299 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 11	Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	48.17
				Vitality Score	51.42
				Physical Component Summary	51.38
				Mental Component Summary	38.70
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 300 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 301 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 302 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0116	NDisc basic	ES/SAF	Baseline (Visit 2a)	Global Health Score	43.59
				Reported Health Transition	2.00
				Physical Functioning Score	23.58
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	13.71
				Bodily Pain Score	15.65
				Mental Health Score	45.90
				Vitality Score	30.12
				Physical Component Summary	31.67
				Mental Component Summary	28.81
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 304 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0116	NDisc basic	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 305 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0116	NDisc basic	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	All of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 306 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	42.00
				Reported Health Transition	1.00
				Physical Functioning Score	34.07
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	46.28
				Bodily Pain Score	41.77
				Mental Health Score	39.08
				Vitality Score	39.59
				Physical Component Summary	39.48
				Mental Component Summary	45.27
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 307 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 308 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 3a	Global Health Score	40.40
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 309 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	31.97
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	46.28
				Bodily Pain Score	37.48
				Mental Health Score	36.81
				Vitality Score	41.95
				Physical Component Summary	37.40
				Mental Component Summary	45.65
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 310 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 311 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 4	Global Health Score	42.00
				Reported Health Transition	2.00
				Physical Functioning Score	29.88
				Role/Physical Score	56.24
				Role Emotional Score	55.34
			Visit 4	Social Functioning Score	46.28
				Bodily Pain Score	33.20

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 312 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	34.54
				Vitality Score	34.85
				Physical Component Summary	35.85
				Mental Component Summary	43.75
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 313 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 314 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 5	Global Health Score	43.59
				Reported Health Transition	3.00
				Physical Functioning Score	34.07
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	39.08
				Vitality Score	41.95

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 315 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	38.62
				Mental Component Summary	44.76
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 316 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 317 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 6	Global Health Score	42.00
				Reported Health Transition	3.00
				Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	51.71
				Bodily Pain Score	37.48
				Mental Health Score	36.81
				Vitality Score	41.95
				Physical Component Summary	41.31
				Mental Component Summary	45.15

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 318 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 319 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 320 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	40.40
				Reported Health Transition	3.00
				Physical Functioning Score	31.97
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	33.63
				Mental Health Score	32.27
				Vitality Score	34.85
				Physical Component Summary	37.02
				Mental Component Summary	40.68
				In general, would you say your health is:	Fair

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 321 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 322 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 323 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	42.00
				Reported Health Transition	2.00
				Physical Functioning Score	27.78
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	30.00
				Bodily Pain Score	25.07
				Mental Health Score	18.64
				Vitality Score	37.22
				Physical Component Summary	36.07
				Mental Component Summary	33.47
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 324 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 325 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 326 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 9	Global Health Score	43.59
				Reported Health Transition	2.00
				Physical Functioning Score	23.58
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	29.35
				Mental Health Score	27.73
				Vitality Score	41.95
				Physical Component Summary	34.14
				Mental Component Summary	40.99
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 328 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 329 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	40.40
				Reported Health Transition	3.00
				Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	34.54
				Vitality Score	32.49
				Physical Component Summary	39.45
				Mental Component Summary	39.89
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 330 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 331 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 332 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	43.59
				Reported Health Transition	3.00
				Physical Functioning Score	27.78
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	32.27
				Vitality Score	34.85
				Physical Component Summary	37.26
				Mental Component Summary	41.22
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 333 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 334 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 335 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	52.20
				Reported Health Transition	1.00
				Physical Functioning Score	30.18
				Role/Physical Score	49.17
				Role Emotional Score	44.81
				Social Functioning Score	46.28
				Bodily Pain Score	37.48
				Mental Health Score	48.17
				Vitality Score	51.42
				Physical Component Summary	36.89
				Mental Component Summary	49.92
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 337 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 338 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 3a	Global Health Score	55.39
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 339 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	48.75
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	57.26
				Vitality Score	60.89
				Physical Component Summary	54.76
				Mental Component Summary	43.77
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 340 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 341 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	48.75
				Role/Physical Score	56.24
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 342 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	59.53
				Vitality Score	65.62
				Physical Component Summary	55.19
				Mental Component Summary	45.93
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 343 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 344 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 5	Global Health Score	59.53
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	65.62

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 345 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	61.64
				Mental Component Summary	43.39
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 346 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 347 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	48.17
				Vitality Score	65.62
				Physical Component Summary	51.79
				Mental Component Summary	42.04

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 348 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 349 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 350 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	57.26
				Vitality Score	63.25
				Physical Component Summary	47.56
				Mental Component Summary	46.36
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 351 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 352 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 353 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 8	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	53.79
				Reported Health Transition	2.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	65.62
				Physical Component Summary	50.77
				Mental Component Summary	45.86
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 354 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 355 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 356 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	55.39
				Reported Health Transition	2.00
				Physical Functioning Score	38.27
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	37.48
				Mental Health Score	52.72
				Vitality Score	53.79
				Physical Component Summary	46.71
				Mental Component Summary	40.76
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 358 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 359 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
			Visit 9	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	53.79
				Reported Health Transition	2.00
				Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	33.20
				Mental Health Score	50.44
				Vitality Score	49.05
				Physical Component Summary	40.18
				Mental Component Summary	50.76
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 360 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 361 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 362 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	53.79
				Reported Health Transition	2.00
				Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	45.90
				Vitality Score	44.32
				Physical Component Summary	46.21
				Mental Component Summary	41.48
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 363 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 364 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 365 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	25.68
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	51.71
				Bodily Pain Score	29.35
				Mental Health Score	41.36
				Vitality Score	49.05
				Physical Component Summary	35.05
				Mental Component Summary	52.99
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 367 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 368 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	59.53
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 369 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	48.75
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	49.90
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	48.17
				Mental Component Summary	44.27
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 370 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 371 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 4	Global Health Score	58.58
				Reported Health Transition	4.00
				Physical Functioning Score	46.66
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	42.19

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 372 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	59.53
				Vitality Score	53.79
				Physical Component Summary	43.52
				Mental Component Summary	47.16
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 373 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 374 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 5	Global Health Score	59.53
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	60.89

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 375 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	52.45
				Mental Component Summary	45.28
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 376 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 377 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	59.53
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	53.18
				Mental Component Summary	40.84

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 378 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 379 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 380 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 7	Global Health Score	57.94
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	52.79
				Mental Component Summary	40.87
				In general, would you say your health is:	Excellent

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 381 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 382 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 383 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	57.94
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	53.42
				Mental Component Summary	40.88
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 384 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 385 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 386 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	59.53
				Reported Health Transition	1.00
				Physical Functioning Score	25.68
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	29.35
				Mental Health Score	54.99
				Vitality Score	53.79
				Physical Component Summary	39.24
				Mental Component Summary	48.40
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 388 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 389 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 3a	Global Health Score	59.53
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 390 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	46.66
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	60.89
				Physical Component Summary	55.46
				Mental Component Summary	45.07
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 391 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 392 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 4	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	55.90

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 393 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	59.53
				Vitality Score	60.89
				Physical Component Summary	49.39
				Mental Component Summary	46.43
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 394 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 395 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 5	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	59.53
				Vitality Score	65.62

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 396 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	52.90
				Mental Component Summary	46.19
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 397 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 398 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	63.25
				Physical Component Summary	52.52
				Mental Component Summary	45.84

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 399 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 400 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 401 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 7	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	59.53
				Vitality Score	65.62
				Physical Component Summary	50.41
				Mental Component Summary	47.06
				In general, would you say your health is:	Excellent

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 402 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 403 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 404 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 8	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	58.52
				Physical Component Summary	52.89
				Mental Component Summary	43.62
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 405 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 406 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 407 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 9	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	58.52
				Physical Component Summary	52.39
				Mental Component Summary	44.72
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 409 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 410 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 10	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	59.53
				Vitality Score	58.52
				Physical Component Summary	50.21
				Mental Component Summary	45.39
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 411 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 412 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 413 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 11	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	60.89
				Physical Component Summary	52.45
				Mental Component Summary	45.28
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 414 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 415 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 416 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	45.82
				Reported Health Transition	3.00
				Physical Functioning Score	29.88
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	24.57
				Bodily Pain Score	33.20
				Mental Health Score	27.73
				Vitality Score	37.22
				Physical Component Summary	40.56
				Mental Component Summary	30.52
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 418 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 419 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 3a	Global Health Score	44.23
				Reported Health Transition	4.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 420 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	27.78
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	37.91
				Mental Health Score	
				Vitality Score	
				Physical Component Summary	
				Mental Component Summary	
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 421 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 422 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	43.59
				Reported Health Transition	3.00
				Physical Functioning Score	29.88
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	33.20

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 423 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	32.27
				Vitality Score	41.95
				Physical Component Summary	36.99
				Mental Component Summary	42.83
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 424 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 425 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 5	Global Health Score	43.59
				Reported Health Transition	3.00
				Physical Functioning Score	36.17
				Role/Physical Score	42.10
				Role Emotional Score	34.27
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	32.27
				Vitality Score	41.95

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 426 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	40.10
				Mental Component Summary	33.56
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 427 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 428 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	42.00
				Reported Health Transition	4.00
				Physical Functioning Score	42.46
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	32.27
				Vitality Score	41.95
				Physical Component Summary	49.36
				Mental Component Summary	25.83

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 429 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 430 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 431 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	44.23
				Reported Health Transition	3.00
				Physical Functioning Score	38.27
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	35.42
				Bodily Pain Score	37.48
				Mental Health Score	32.27
				Vitality Score	41.95
				Physical Component Summary	44.13
				Mental Component Summary	34.44
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 432 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 433 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 434 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	40.40
				Reported Health Transition	2.00
				Physical Functioning Score	34.07
				Role/Physical Score	56.24
				Role Emotional Score	34.27
				Social Functioning Score	40.85
				Bodily Pain Score	29.35
				Mental Health Score	32.27
				Vitality Score	41.95
				Physical Component Summary	40.80
				Mental Component Summary	33.14
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 435 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 436 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 437 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
			Visit 9	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
				Global Health Score	40.40
				Reported Health Transition	3.00
				Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	37.48
				Mental Health Score	23.18
				Vitality Score	34.85
				Physical Component Summary	43.84
				Mental Component Summary	32.51
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 438 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 439 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 440 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 10	Global Health Score	38.81
				Reported Health Transition	2.00
				Physical Functioning Score	23.58
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	24.57
				Bodily Pain Score	29.35
				Mental Health Score	14.09
				Vitality Score	27.75
				Physical Component Summary	35.63
				Mental Component Summary	28.18
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 441 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 442 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 443 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0124	NDisc plus	ES/SAF	Baseline (Visit 2a)	Global Health Score	42.00
				Reported Health Transition	1.00
				Physical Functioning Score	31.97
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	24.57
				Bodily Pain Score	28.92
				Mental Health Score	20.91
				Vitality Score	30.12
				Physical Component Summary	38.41
				Mental Component Summary	30.11
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 445 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0124	NDisc plus	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 446 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0124	NDisc plus	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 447 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	25.68
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	37.48
				Mental Health Score	45.90
				Vitality Score	41.95
				Physical Component Summary	42.50
				Mental Component Summary	39.01
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 448 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 449 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	50.61
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 450 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	38.27
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	51.61
				Mental Health Score	39.08
				Vitality Score	37.22
				Physical Component Summary	47.57
				Mental Component Summary	30.68
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 452 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 453 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 5	Mental Health Score	52.72
				Vitality Score	46.69
				Physical Component Summary	45.52
				Mental Component Summary	41.27
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 455 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 6	Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	58.52

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 456 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	50.08
				Mental Component Summary	43.68
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 457 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 458 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	59.53
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	51.65
				Mental Component Summary	41.52

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 459 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 460 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 461 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 8	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	48.17
				Vitality Score	46.69
				Physical Component Summary	46.57
				Mental Component Summary	39.03
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 462 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 463 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 464 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 9	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	41.77
				Mental Health Score	43.63
				Vitality Score	39.59
				Physical Component Summary	44.19
				Mental Component Summary	36.14
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 465 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 466 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 467 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 10	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	45.18
				Reported Health Transition	2.00
				Physical Functioning Score	38.27
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	24.21
				Mental Health Score	39.08
				Vitality Score	34.85
				Physical Component Summary	42.41
				Mental Component Summary	31.13
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 469 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 470 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 11	Global Health Score	50.61
				Reported Health Transition	2.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	34.27
				Social Functioning Score	57.14
				Bodily Pain Score	46.05
				Mental Health Score	41.36
				Vitality Score	44.32
				Physical Component Summary	44.65
				Mental Component Summary	39.85
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 471 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 472 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 473 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	48.37
				Reported Health Transition	1.00
				Physical Functioning Score	21.49
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	33.20
				Mental Health Score	34.54
				Vitality Score	27.75
				Physical Component Summary	39.79
				Mental Component Summary	28.73
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 475 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 476 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	52.20
				Reported Health Transition	4.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 477 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	34.27
				Social Functioning Score	46.28
				Bodily Pain Score	42.19
				Mental Health Score	35.68
				Vitality Score	34.85
				Physical Component Summary	51.27
				Mental Component Summary	30.74
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 478 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 479 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	39.44
				Reported Health Transition	4.00
				Physical Functioning Score	42.46
				Role/Physical Score	49.17
				Role Emotional Score	55.34
				Social Functioning Score	46.28
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 480 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	50.44
				Vitality Score	37.22
				Physical Component Summary	38.84
				Mental Component Summary	48.75
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 481 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 482 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	47.42
				Reported Health Transition	4.00
				Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	33.20
				Mental Health Score	25.45
				Vitality Score	30.12

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 483 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	45.38
				Mental Component Summary	31.84
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 484 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 485 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	39.08
				Vitality Score	41.95
				Physical Component Summary	50.13
				Mental Component Summary	32.68

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 486 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 487 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 488 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	52.72
				Vitality Score	49.05
				Physical Component Summary	46.62
				Mental Component Summary	40.88
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 489 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 490 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 491 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 8	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	45.90
				Vitality Score	56.15
				Physical Component Summary	52.61
				Mental Component Summary	38.14
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 492 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 493 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 494 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	53.79
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	50.76
				Mental Health Score	34.54
				Vitality Score	39.59
				Physical Component Summary	51.23
				Mental Component Summary	29.86
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 496 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 497 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	34.54
				Vitality Score	41.95
				Physical Component Summary	51.15
				Mental Component Summary	30.89
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 498 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 499 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 500 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	41.77
				Mental Health Score	36.81
				Vitality Score	37.22
				Physical Component Summary	46.56
				Mental Component Summary	30.34
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 501 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 502 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 503 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	56.98
				Reported Health Transition	1.00
				Physical Functioning Score	34.07
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	29.35
				Mental Health Score	52.72
				Vitality Score	44.32
				Physical Component Summary	42.51
				Mental Component Summary	38.80
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 505 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 506 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	50.61
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 507 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	57.26
				Vitality Score	58.52
				Physical Component Summary	47.59
				Mental Component Summary	44.91
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 508 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 509 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 4	Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 510 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	59.53
				Vitality Score	63.25
				Physical Component Summary	47.06
				Mental Component Summary	47.47
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 511 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 512 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	49.01
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	59.53
				Vitality Score	58.52

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 513 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	45.33
				Mental Component Summary	46.45
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 514 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 515 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	52.72
				Vitality Score	58.52
				Physical Component Summary	46.80
				Mental Component Summary	43.54

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 516 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 517 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 518 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	59.53
				Vitality Score	56.15
				Physical Component Summary	47.82
				Mental Component Summary	45.40
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 519 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 520 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 521 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	47.42
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	50.76
				Mental Health Score	54.99
				Vitality Score	58.52
				Physical Component Summary	45.67
				Mental Component Summary	44.35
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 523 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 524 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 9	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	41.77
				Mental Health Score	52.72
				Vitality Score	53.79
				Physical Component Summary	42.99
				Mental Component Summary	43.88
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 525 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 526 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 527 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	41.77
				Mental Health Score	52.72
				Vitality Score	49.05
				Physical Component Summary	43.88
				Mental Component Summary	40.39
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 528 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 529 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 530 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	55.90
				Mental Health Score	50.44
				Vitality Score	51.42
				Physical Component Summary	49.33
				Mental Component Summary	38.44
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 531 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 532 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 533 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	45.82
				Reported Health Transition	2.00
				Physical Functioning Score	31.97
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	33.20
				Mental Health Score	43.63
				Vitality Score	39.59
				Physical Component Summary	41.85
				Mental Component Summary	36.47
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 535 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 536 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 3a	Global Health Score	45.82
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 537 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	48.75
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	51.61
				Mental Health Score	43.63
				Vitality Score	44.32
				Physical Component Summary	52.51
				Mental Component Summary	31.35
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 538 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 539 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	47.42
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 540 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	48.17
				Vitality Score	53.79
				Physical Component Summary	46.42
				Mental Component Summary	40.33
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 541 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 542 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	47.42
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	45.90
				Vitality Score	51.42

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 543 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	48.21
				Mental Component Summary	38.25
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 544 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 545 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 6	Global Health Score	44.23
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	45.90
				Vitality Score	44.32
				Physical Component Summary	46.74
				Mental Component Summary	36.56

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 546 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 547 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 548 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 7	Global Health Score	50.61
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	50.76
				Mental Health Score	45.90
				Vitality Score	49.05
				Physical Component Summary	47.35
				Mental Component Summary	36.68
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 549 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 550 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 551 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	49.01
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	50.76
				Mental Health Score	50.44
				Vitality Score	53.79
				Physical Component Summary	46.04
				Mental Component Summary	41.49
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 553 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 554 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
			Visit 9	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	50.61
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	45.90
				Vitality Score	49.05
				Physical Component Summary	48.51
				Mental Component Summary	36.12
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 556 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 557 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	50.61
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	50.44
				Vitality Score	46.69
				Physical Component Summary	44.88
				Mental Component Summary	40.21
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 558 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 559 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 560 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	34.27
				Social Functioning Score	51.71
				Bodily Pain Score	46.48
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	42.57
				Mental Component Summary	47.09
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 561 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 562 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 563 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	47.42
				Reported Health Transition	3.00
				Physical Functioning Score	26.85
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	54.18
				Mental Health Score	50.44
				Vitality Score	46.69
				Physical Component Summary	42.91
				Mental Component Summary	42.90
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 565 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 566 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 4	Global Health Score	52.20
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 567 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	51.71
				Bodily Pain Score	46.48
				Mental Health Score	48.17
				Vitality Score	46.69
				Physical Component Summary	46.37
				Mental Component Summary	46.18
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 568 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 569 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	49.01
				Reported Health Transition	4.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 5	Social Functioning Score	51.71
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 570 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 5	Mental Health Score	48.17
				Vitality Score	53.79
				Physical Component Summary	45.97
				Mental Component Summary	39.33
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 571 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 572 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 6	Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	46.66
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	56.15

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 573 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	49.24
				Mental Component Summary	42.20
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 574 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 575 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	53.79
				Physical Component Summary	51.34
				Mental Component Summary	41.30

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 576 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 577 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 578 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 8	Global Health Score	49.01
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	53.79
				Physical Component Summary	49.89
				Mental Component Summary	38.86
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 579 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 580 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 581 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	50.61
				Reported Health Transition	2.00
				Physical Functioning Score	38.27
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	38.42
				Mental Component Summary	46.92
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 582 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 583 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 584 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	44.23
				Reported Health Transition	2.00
				Physical Functioning Score	36.17
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	37.48
				Mental Health Score	48.17
				Vitality Score	44.32
				Physical Component Summary	41.28
				Mental Component Summary	37.85
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 586 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 587 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 11	Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	59.53
				Vitality Score	56.15
				Physical Component Summary	49.90
				Mental Component Summary	44.85
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 588 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 589 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 590 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	25.68
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	29.35
				Mental Health Score	54.99
				Vitality Score	46.69
				Physical Component Summary	35.20
				Mental Component Summary	44.77
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 592 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 593 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	55.39
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 594 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	48.75
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	57.26
				Vitality Score	58.52
				Physical Component Summary	47.24
				Mental Component Summary	45.82
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 595 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 596 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 597 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	57.26
				Vitality Score	58.52
				Physical Component Summary	45.40
				Mental Component Summary	45.77
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 599 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	54.18
				Mental Health Score	57.26
				Vitality Score	56.15

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 600 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	47.68
				Mental Component Summary	44.90
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 601 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 602 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	57.94
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	58.52
				Physical Component Summary	49.93
				Mental Component Summary	43.69

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 603 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 604 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 605 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 7	Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	58.52
				Physical Component Summary	51.86
				Mental Component Summary	43.04
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 606 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 607 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 608 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 8	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	56.98
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	56.15
				Physical Component Summary	50.40
				Mental Component Summary	44.07
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 609 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 610 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 611 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 9	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	57.26
				Vitality Score	58.52
				Physical Component Summary	47.90
				Mental Component Summary	45.31
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 613 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 614 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	49.22
				Mental Component Summary	43.17
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 615 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 616 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 617 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	59.53
				Vitality Score	53.79
				Physical Component Summary	47.75
				Mental Component Summary	44.85
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 618 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 619 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 620 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	23.58
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	19.93
				Mental Health Score	25.45
				Vitality Score	34.85
				Physical Component Summary	33.95
				Mental Component Summary	40.43
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 622 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 623 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	55.39
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 624 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	43.63
				Vitality Score	51.42
				Physical Component Summary	52.88
				Mental Component Summary	36.36
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 626 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 627 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	48.17
				Vitality Score	49.05
				Physical Component Summary	53.59
				Mental Component Summary	37.04
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 629 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	48.17
				Vitality Score	51.42

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 630 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	50.68
				Mental Component Summary	38.31
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 631 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 632 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	53.79
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	53.79
				Physical Component Summary	52.32
				Mental Component Summary	40.39

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 633 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 634 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 635 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	53.79
				Physical Component Summary	52.82
				Mental Component Summary	39.28
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 636 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 637 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 638 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	57.94
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	51.11
				Mental Component Summary	40.43
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 639 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 640 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 641 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
			Visit 9	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	48.17
				Vitality Score	51.42
				Physical Component Summary	51.08
				Mental Component Summary	38.29
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 642 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 643 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 644 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	48.17
				Vitality Score	49.05
				Physical Component Summary	53.19
				Mental Component Summary	37.07
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 645 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 646 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 647 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	49.05
				Physical Component Summary	53.88
				Mental Component Summary	38.09
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 648 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 649 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 650 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	52.20
				Reported Health Transition	2.00
				Physical Functioning Score	34.07
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	30.00
				Bodily Pain Score	33.20
				Mental Health Score	36.81
				Vitality Score	34.85
				Physical Component Summary	45.86
				Mental Component Summary	25.63
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 652 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 653 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 4	Global Health Score	53.79
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 654 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	48.75
				Role/Physical Score	35.03
				Role Emotional Score	34.27
				Social Functioning Score	40.85
				Bodily Pain Score	42.19
				Mental Health Score	45.90
				Vitality Score	44.32
				Physical Component Summary	44.05
				Mental Component Summary	38.10
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 655 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 656 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	56.35
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 657 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 5	Mental Health Score	50.44
				Vitality Score	44.32
				Physical Component Summary	53.19
				Mental Component Summary	37.02
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 659 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 6	Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	60.89

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 660 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	49.36
				Mental Component Summary	44.29
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 661 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 662 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	56.35
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	50.44
				Vitality Score	58.52
				Physical Component Summary	50.53
				Mental Component Summary	41.51

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 663 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 664 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 665 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	53.16
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	53.79
				Physical Component Summary	52.16
				Mental Component Summary	40.40
				In general, would you say your health is:	Excellent

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 666 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 667 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 668 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
			Visit 9	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	47.93
				Mental Component Summary	43.68
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 670 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 671 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
			Visit 10	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	50.44
				Vitality Score	58.52
				Physical Component Summary	49.89
				Mental Component Summary	41.55
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 672 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 673 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 674 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	53.79
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	50.44
				Vitality Score	58.52
				Physical Component Summary	52.38
				Mental Component Summary	40.67
		In general, would you say your health is:	Very good		
		Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago		
		Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all		
		Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all		
		Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 675 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 676 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 677 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0133	NDisc plus	ES/SAF	Baseline (Visit 2a)	Global Health Score	44.23
				Reported Health Transition	1.00
				Physical Functioning Score	31.97
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	29.35
				Mental Health Score	32.27
				Vitality Score	34.85
				Physical Component Summary	36.65
				Mental Component Summary	39.58
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 679 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0133	NDisc plus	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 680 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0133	NDisc plus	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 681 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0134	NDisc basic	ES/SAF	Baseline (Visit 2a)	Global Health Score	45.82
				Reported Health Transition	2.00
				Physical Functioning Score	34.07
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	40.85
				Bodily Pain Score	29.35
				Mental Health Score	36.81
				Vitality Score	34.85
				Physical Component Summary	38.92
				Mental Component Summary	38.17
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 682 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0134	NDisc basic	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 683 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0134	NDisc basic	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 684 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	53.79
				Reported Health Transition	2.00
				Physical Functioning Score	29.88
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	37.48
				Mental Health Score	41.36
				Vitality Score	32.49
				Physical Component Summary	44.73
				Mental Component Summary	29.26
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 685 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 686 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	52.20
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 687 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	42.46
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	42.19
				Mental Health Score	41.36
				Vitality Score	41.95
				Physical Component Summary	43.86
				Mental Component Summary	35.15
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 688 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 689 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	48.75
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	47.33

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 690 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	52.72
				Vitality Score	49.05
				Physical Component Summary	49.93
				Mental Component Summary	39.42
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 691 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 692 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 5	Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	52.72
				Vitality Score	46.69

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 693 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	49.65
				Mental Component Summary	39.98
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 694 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 695 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	46.66
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	41.36
				Vitality Score	41.95
				Physical Component Summary	52.08
				Mental Component Summary	29.09

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 696 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 697 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 698 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 7	Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	50.44
				Vitality Score	49.05
				Physical Component Summary	46.88
				Mental Component Summary	40.67
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 699 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 700 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 701 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	55.39
				Reported Health Transition	4.00
				Physical Functioning Score	48.75
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	45.69
				Mental Component Summary	43.93
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 703 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 704 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	53.79
				Reported Health Transition	2.00
				Physical Functioning Score	46.66
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	37.48
				Mental Health Score	45.90
				Vitality Score	41.95
				Physical Component Summary	48.55
				Mental Component Summary	33.63
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 706 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 707 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	50.61
				Reported Health Transition	2.00
				Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	33.20
				Mental Health Score	39.08
				Vitality Score	41.95
				Physical Component Summary	49.45
				Mental Component Summary	31.85
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 708 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 709 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 710 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 11	Global Health Score	53.79
				Reported Health Transition	4.00
				Physical Functioning Score	48.75
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	42.19
				Mental Health Score	36.81
				Vitality Score	44.32
				Physical Component Summary	55.41
				Mental Component Summary	30.88
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 711 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 712 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 713 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	44.23
				Reported Health Transition	1.00
				Physical Functioning Score	31.97
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	30.00
				Bodily Pain Score	33.63
				Mental Health Score	34.54
				Vitality Score	39.59
				Physical Component Summary	39.71
				Mental Component Summary	35.35
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 715 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 716 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	45.82
				Reported Health Transition	4.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 717 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	38.27
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	48.17
				Vitality Score	41.95
				Physical Component Summary	42.54
				Mental Component Summary	35.33
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 718 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 719 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 4	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	42.46
				Role/Physical Score	42.10
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	51.71
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 720 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	52.72
				Vitality Score	53.79
				Physical Component Summary	45.14
				Mental Component Summary	42.19
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 721 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 722 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	47.42
				Reported Health Transition	4.00
				Physical Functioning Score	31.97
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	33.63
				Mental Health Score	54.99
				Vitality Score	46.69

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 723 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	35.11
				Mental Component Summary	45.34
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 724 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 725 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 6	Global Health Score	41.04
				Reported Health Transition	2.00
				Physical Functioning Score	29.88
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	37.48
				Mental Health Score	50.44
				Vitality Score	44.32
				Physical Component Summary	37.40
				Mental Component Summary	37.53

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 726 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 727 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 728 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	44.23
				Reported Health Transition	3.00
				Physical Functioning Score	31.97
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	33.63
				Mental Health Score	32.27
				Vitality Score	44.32
				Physical Component Summary	44.35
				Mental Component Summary	27.68
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 729 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 730 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 731 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 8	Global Health Score	41.60
				Reported Health Transition	
				Physical Functioning Score	26.85
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	46.28
				Bodily Pain Score	29.35
				Mental Health Score	39.08
				Vitality Score	37.22
				Physical Component Summary	32.30
				Mental Component Summary	47.59
				In general, would you say your health is:	
				Compared to one year ago, how would you rate your health in general now?	

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 733 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 734 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 9	Global Health Score	39.44
				Reported Health Transition	2.00
				Physical Functioning Score	29.88
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	29.35
				Mental Health Score	30.00
				Vitality Score	32.49
				Physical Component Summary	41.07
				Mental Component Summary	24.76
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 736 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 737 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 10	Global Health Score	47.42
				Reported Health Transition	3.00
				Physical Functioning Score	29.88
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	29.35
				Mental Health Score	41.36
				Vitality Score	39.59
				Physical Component Summary	38.23
				Mental Component Summary	34.16
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 738 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 739 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 740 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 11	Global Health Score	41.04
				Reported Health Transition	3.00
				Physical Functioning Score	27.78
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	37.48
				Mental Health Score	30.00
				Vitality Score	39.59
				Physical Component Summary	38.40
				Mental Component Summary	27.84
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 741 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 742 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 743 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	53.79
				Reported Health Transition	1.00
				Physical Functioning Score	44.56
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	37.91
				Mental Health Score	54.99
				Vitality Score	53.79
				Physical Component Summary	38.60
				Mental Component Summary	46.80
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 745 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 746 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	55.39
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 747 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	43.63
				Vitality Score	51.42
				Physical Component Summary	55.76
				Mental Component Summary	34.42
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 748 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 749 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 750 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	45.90
				Vitality Score	51.42
				Physical Component Summary	48.84
				Mental Component Summary	38.54
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 751 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 752 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	45.90
				Vitality Score	58.52

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 753 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	49.05
				Mental Component Summary	40.21
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 754 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 755 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	50.44
				Vitality Score	53.79
				Physical Component Summary	47.91
				Mental Component Summary	41.31

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 756 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 757 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 758 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	55.39
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	48.17
				Vitality Score	58.52
				Physical Component Summary	51.68
				Mental Component Summary	39.94
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 759 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 760 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 761 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	48.17
				Vitality Score	58.52
				Physical Component Summary	49.08
				Mental Component Summary	39.40
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 762 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 763 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 764 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	48.17
				Vitality Score	53.79
				Physical Component Summary	53.72
				Mental Component Summary	38.15
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 766 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 767 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	56.98
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	50.76
				Mental Health Score	50.44
				Vitality Score	58.52
				Physical Component Summary	49.99
				Mental Component Summary	40.05
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 768 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 769 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 770 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	56.98
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	45.90
				Vitality Score	56.15
				Physical Component Summary	51.19
				Mental Component Summary	37.21
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 771 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 772 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 773 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	40.36
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	41.64
				Mental Component Summary	43.31
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 775 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 776 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	56.35
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 777 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	55.05
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	59.26
				Mental Component Summary	38.55
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 778 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 779 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	59.53
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 780 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 5	Mental Health Score	52.72
				Vitality Score	58.52
				Physical Component Summary	53.00
				Mental Component Summary	41.89
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 782 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 6	Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	65.62

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 783 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	51.95
				Mental Component Summary	46.43
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 784 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 785 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	59.53
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	58.52
				Physical Component Summary	52.89
				Mental Component Summary	43.62

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 786 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 787 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 788 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 8	Global Health Score	57.94
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	52.79
				Mental Component Summary	40.87
				In general, would you say your health is:	Excellent

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 789 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 790 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 791 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 9	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	63.25
				Physical Component Summary	53.02
				Mental Component Summary	44.73
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 792 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 793 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 794 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 10	Global Health Score	56.35
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	56.15
				Physical Component Summary	52.02
				Mental Component Summary	43.11
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 796 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 797 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	53.32
				Mental Component Summary	41.96
		In general, would you say your health is:	Excellent		
		Compared to one year ago, how would you rate your health in general now?	About the same as one year ago		
		Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all		
		Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all		
		Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 798 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 799 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 800 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	45.82
				Reported Health Transition	1.00
				Physical Functioning Score	21.49
				Role/Physical Score	56.24
				Role Emotional Score	34.27
				Social Functioning Score	46.28
				Bodily Pain Score	19.93
				Mental Health Score	25.45
				Vitality Score	27.75
				Physical Component Summary	34.88
				Mental Component Summary	31.68
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 802 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 803 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	55.39
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 804 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	46.08
				Mental Component Summary	44.55
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 805 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 806 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	55.39
				Reported Health Transition	2.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 807 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	49.72
				Mental Component Summary	42.07
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 808 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 809 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	56.98
				Reported Health Transition	2.00
				Physical Functioning Score	55.05
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	55.90
				Mental Health Score	52.72
				Vitality Score	56.15

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 810 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	57.61
				Mental Component Summary	37.97
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 811 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 812 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	56.98
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	52.72
				Vitality Score	58.52
				Physical Component Summary	52.67
				Mental Component Summary	41.73

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 813 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 814 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 815 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	56.15
				Physical Component Summary	51.91
				Mental Component Summary	40.75
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 816 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 817 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 818 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	49.01
				Reported Health Transition	2.00
				Physical Functioning Score	48.75
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	37.48
				Mental Health Score	43.63
				Vitality Score	46.69
				Physical Component Summary	51.37
				Mental Component Summary	32.36
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 820 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 821 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 9	Global Health Score	55.39
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	48.17
				Vitality Score	49.05
				Physical Component Summary	50.76
				Mental Component Summary	38.22
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 823 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 824 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	56.98
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	51.21
				Mental Component Summary	42.76
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 825 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 826 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 827 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	38.27
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	51.71
				Bodily Pain Score	33.20
				Mental Health Score	39.08
				Vitality Score	41.95
				Physical Component Summary	40.71
				Mental Component Summary	47.02
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 829 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 830 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 3a	Global Health Score	52.20
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 831 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	45.49
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	51.61
				Mental Health Score	43.63
				Vitality Score	44.32
				Physical Component Summary	49.21
				Mental Component Summary	41.93
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 832 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 833 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	48.75
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	46.28
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 834 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	36.81
				Vitality Score	41.95
				Physical Component Summary	51.95
				Mental Component Summary	40.23
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 836 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	52.72
				Vitality Score	56.15

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 837 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	47.47
				Mental Component Summary	42.97
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 838 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 839 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 6	Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	50.44
				Vitality Score	53.79
				Physical Component Summary	47.02
				Mental Component Summary	41.79

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 840 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 841 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 842 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	47.08
				Mental Component Summary	42.99
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 843 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 844 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 845 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	50.44
				Vitality Score	56.15
				Physical Component Summary	47.22
				Mental Component Summary	40.45
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 846 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 847 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 848 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	50.61
				Reported Health Transition	4.00
				Physical Functioning Score	46.66
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	50.44
				Vitality Score	51.42
				Physical Component Summary	44.83
				Mental Component Summary	41.90
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 850 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 851 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	50.61
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	42.19
				Mental Health Score	43.63
				Vitality Score	46.69
				Physical Component Summary	50.03
				Mental Component Summary	34.11
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 852 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 853 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 854 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	52.20
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	47.57
				Mental Component Summary	42.53
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 855 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 856 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 857 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	53.16
				Reported Health Transition	1.00
				Physical Functioning Score	17.29
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	19.14
				Bodily Pain Score	19.93
				Mental Health Score	23.18
				Vitality Score	25.39
				Physical Component Summary	31.52
				Mental Component Summary	32.72
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 859 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 860 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	47.42
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 861 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	34.07
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	24.57
				Bodily Pain Score	37.48
				Mental Health Score	34.54
				Vitality Score	41.95
				Physical Component Summary	40.71
				Mental Component Summary	38.11
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 862 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 863 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	53.79
				Reported Health Transition	2.00
				Physical Functioning Score	42.46
				Role/Physical Score	56.24
				Role Emotional Score	55.34
			Visit 5	Social Functioning Score	46.28
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 864 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 5	Mental Health Score	52.72
				Vitality Score	49.05
				Physical Component Summary	44.74
				Mental Component Summary	51.55
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 865 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 866 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 6	Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	57.26
				Vitality Score	53.79

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 867 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	48.25
				Mental Component Summary	43.74
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 868 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 869 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	45.30
				Mental Component Summary	43.02

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 870 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 871 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 872 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	57.26
				Vitality Score	56.15
				Physical Component Summary	47.41
				Mental Component Summary	44.66
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 873 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 874 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 875 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 9	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	57.26
				Vitality Score	56.15
				Physical Component Summary	46.22
				Mental Component Summary	44.73
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 876 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 877 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 878 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 10	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	50.11
				Mental Component Summary	42.69
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 880 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 881 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	52.72
				Vitality Score	46.69
				Physical Component Summary	46.88
				Mental Component Summary	40.85
		In general, would you say your health is:	Good		
		Compared to one year ago, how would you rate your health in general now?	About the same as one year ago		
		Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little		
		Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little		
		Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 882 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 883 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 884 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	49.01
				Reported Health Transition	2.00
				Physical Functioning Score	34.07
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	37.91
				Mental Health Score	32.27
				Vitality Score	32.49
				Physical Component Summary	41.39
				Mental Component Summary	37.63
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 886 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 887 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	56.98
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 888 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	57.26
				Vitality Score	56.15
				Physical Component Summary	47.76
				Mental Component Summary	44.67
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 889 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 890 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	35.03
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 891 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	57.26
				Vitality Score	56.15
				Physical Component Summary	49.75
				Mental Component Summary	44.25
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 892 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 893 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 5	Global Health Score	58.58
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	59.53
				Vitality Score	58.52

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 894 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	47.72
				Mental Component Summary	46.30
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 895 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 896 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	59.53
				Vitality Score	56.15
				Physical Component Summary	47.65
				Mental Component Summary	45.75

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 897 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 898 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 899 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	59.53
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	59.53
				Vitality Score	56.15
				Physical Component Summary	48.78
				Mental Component Summary	45.25
				In general, would you say your health is:	Excellent

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 900 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 901 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 902 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	50.09
				Mental Component Summary	40.49
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 904 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 905 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 9	Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	59.53
				Vitality Score	56.15
				Physical Component Summary	47.65
				Mental Component Summary	45.75
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 906 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 907 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 908 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 10	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	46.66
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	37.48
				Mental Health Score	59.53
				Vitality Score	53.79
				Physical Component Summary	45.40
				Mental Component Summary	45.98
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 909 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 910 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 911 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	49.01
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	41.77
				Mental Health Score	43.63
				Vitality Score	46.69
				Physical Component Summary	46.97
				Mental Component Summary	36.51
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 912 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 913 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 914 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	52.20
				Reported Health Transition	2.00
				Physical Functioning Score	34.07
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	37.48
				Mental Health Score	45.90
				Vitality Score	46.69
				Physical Component Summary	39.45
				Mental Component Summary	47.59
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 916 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 917 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	53.79
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 918 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	48.75
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	52.72
				Vitality Score	53.79
				Physical Component Summary	46.08
				Mental Component Summary	43.03
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 919 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 920 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	49.01
				Reported Health Transition	4.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 921 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	54.99
				Vitality Score	58.52
				Physical Component Summary	42.93
				Mental Component Summary	45.71
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 922 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 923 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 5	Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	52.72
				Vitality Score	53.79

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 924 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	45.32
				Mental Component Summary	42.97
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 925 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 926 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	48.17
				Vitality Score	53.79
				Physical Component Summary	47.52
				Mental Component Summary	40.69

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 927 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 928 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 929 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	48.17
				Vitality Score	56.15
				Physical Component Summary	48.55
				Mental Component Summary	40.85
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 930 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 931 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 932 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 8	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	50.61
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	48.17
				Vitality Score	56.15
				Physical Component Summary	49.53
				Mental Component Summary	39.94
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 934 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 935 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	48.17
				Vitality Score	51.42
				Physical Component Summary	49.40
				Mental Component Summary	38.82
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 936 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 937 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 938 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	58.52
				Physical Component Summary	48.10
				Mental Component Summary	43.80
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 939 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 940 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 941 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	48.17
				Vitality Score	53.79
				Physical Component Summary	49.46
				Mental Component Summary	39.38
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 942 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 943 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 944 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	52.20
				Reported Health Transition	2.00
				Physical Functioning Score	31.97
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	29.35
				Mental Health Score	32.27
				Vitality Score	32.49
				Physical Component Summary	44.60
				Mental Component Summary	26.64
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 946 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 947 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	53.79
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 948 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	45.90
				Vitality Score	49.05
				Physical Component Summary	52.80
				Mental Component Summary	36.44
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 949 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 950 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 4	Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	62.75

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 951 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	48.17
				Vitality Score	56.15
				Physical Component Summary	54.59
				Mental Component Summary	38.66
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 952 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 953 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 5	Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	45.90
				Vitality Score	53.79

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 954 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	55.02
				Mental Component Summary	37.00
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 955 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 956 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	53.16
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	43.63
				Vitality Score	53.79
				Physical Component Summary	54.17
				Mental Component Summary	35.98

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 957 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 958 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 959 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 7	Global Health Score	59.53
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	48.17
				Vitality Score	53.79
				Physical Component Summary	54.76
				Mental Component Summary	38.09
				In general, would you say your health is:	Excellent

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 960 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 961 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 962 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 8	Global Health Score	59.53
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	45.90
				Vitality Score	56.15
				Physical Component Summary	55.33
				Mental Component Summary	37.54
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 964 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 965 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 9	Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	49.05
				Physical Component Summary	53.88
				Mental Component Summary	38.09
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 966 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 967 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 968 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 10	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	48.75
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	41.77
				Mental Health Score	50.44
				Vitality Score	41.95
				Physical Component Summary	47.63
				Mental Component Summary	38.70
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 969 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 970 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 971 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	56.35
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	48.17
				Vitality Score	49.05
				Physical Component Summary	53.82
				Mental Component Summary	37.03
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 972 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 973 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 974 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	49.97
				Reported Health Transition	3.00
				Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	33.20
				Mental Health Score	50.44
				Vitality Score	37.22
				Physical Component Summary	43.09
				Mental Component Summary	38.20
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 976 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 977 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	55.39
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 978 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	40.83
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	37.48
				Mental Health Score	52.72
				Vitality Score	53.79
				Physical Component Summary	45.23
				Mental Component Summary	43.96
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 979 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 980 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 4	Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 981 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	48.17
				Vitality Score	54.58
				Physical Component Summary	45.51
				Mental Component Summary	41.40
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 982 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 983 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	54.99
				Vitality Score	63.25

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 984 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	47.97
				Mental Component Summary	45.69
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 985 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 986 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	50.76
				Mental Health Score	57.26
				Vitality Score	56.15
				Physical Component Summary	47.88
				Mental Component Summary	44.73

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 987 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 988 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 989 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	59.53
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	35.03
				Role Emotional Score	34.27
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	57.26
				Vitality Score	63.25
				Physical Component Summary	49.53
				Mental Component Summary	50.06
				In general, would you say your health is:	Excellent

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 990 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 991 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 992 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 8	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	59.53
				Vitality Score	60.89
				Physical Component Summary	49.39
				Mental Component Summary	46.43
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 993 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 994 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 995 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 9	Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	52.72
				Vitality Score	53.79
				Physical Component Summary	50.45
				Mental Component Summary	41.46
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 997 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 998 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 10	Global Health Score	41.04
				Reported Health Transition	2.00
				Physical Functioning Score	50.85
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	29.35
				Mental Health Score	48.17
				Vitality Score	41.95
				Physical Component Summary	46.46
				Mental Component Summary	36.80
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 999 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1000 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1001 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 11	Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	59.53
				Vitality Score	60.89
				Physical Component Summary	47.79
				Mental Component Summary	46.86
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1002 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1003 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1004 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	35.62
				Reported Health Transition	1.00
				Physical Functioning Score	34.07
				Role/Physical Score	49.17
				Role Emotional Score	34.27
				Social Functioning Score	35.42
				Bodily Pain Score	29.35
				Mental Health Score	30.00
				Vitality Score	34.85
				Physical Component Summary	37.46
				Mental Component Summary	29.86
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1006 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1007 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 4	Global Health Score	44.23
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1008 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	48.75
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	47.33
				Mental Health Score	41.36
				Vitality Score	49.05
				Physical Component Summary	48.90
				Mental Component Summary	32.67
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1010 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	47.42
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 5	Social Functioning Score	57.14
				Bodily Pain Score	42.19

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1011 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 5	Mental Health Score	45.90
				Vitality Score	53.79
				Physical Component Summary	43.04
				Mental Component Summary	40.62
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1013 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 6	Global Health Score	44.23
				Reported Health Transition	4.00
				Physical Functioning Score	46.66
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	37.48
				Mental Health Score	36.81
				Vitality Score	41.95

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1014 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	50.65
				Mental Component Summary	28.49
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1015 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1016 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	41.04
				Reported Health Transition	5.00
				Physical Functioning Score	44.56
				Role/Physical Score	49.17
				Role Emotional Score	34.27
				Social Functioning Score	46.28
				Bodily Pain Score	37.48
				Mental Health Score	30.00
				Vitality Score	37.22
				Physical Component Summary	45.83
				Mental Component Summary	30.04

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1017 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1018 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1019 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 8	Global Health Score	44.23
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	46.48
				Mental Health Score	45.90
				Vitality Score	46.69
				Physical Component Summary	46.11
				Mental Component Summary	35.68
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1020 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1021 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1022 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	42.63
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	42.10
				Role Emotional Score	34.27
				Social Functioning Score	40.85
				Bodily Pain Score	42.19
				Mental Health Score	39.08
				Vitality Score	44.32
				Physical Component Summary	47.03
				Mental Component Summary	33.13
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1023 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1024 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1025 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 10	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	39.44
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	35.03
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	33.20
				Mental Health Score	30.00
				Vitality Score	37.22
				Physical Component Summary	37.76
				Mental Component Summary	38.47
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1027 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1028 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 11	Global Health Score	44.23
				Reported Health Transition	3.00
				Physical Functioning Score	48.75
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	39.08
				Vitality Score	41.95
				Physical Component Summary	46.11
				Mental Component Summary	29.40
		In general, would you say your health is:	Good		
		Compared to one year ago, how would you rate your health in general now?	About the same as one year ago		
		Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little		
		Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little		
		Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1029 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1030 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1031 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	55.39
				Reported Health Transition	1.00
				Physical Functioning Score	36.17
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	29.35
				Mental Health Score	43.63
				Vitality Score	46.69
				Physical Component Summary	42.51
				Mental Component Summary	38.28
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1033 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1034 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	52.20
				Reported Health Transition	4.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1035 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	53.79
				Physical Component Summary	49.14
				Mental Component Summary	43.58
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1036 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1037 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	57.94
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1038 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	54.99
				Vitality Score	58.52
				Physical Component Summary	52.99
				Mental Component Summary	42.54
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1039 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1040 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 5	Global Health Score	56.35
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	53.79

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1041 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	52.46
				Mental Component Summary	41.45
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1042 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1043 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	59.53
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	53.79
				Physical Component Summary	52.75
				Mental Component Summary	42.50

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1044 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1045 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1046 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 7	Global Health Score	59.53
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	63.25
				Physical Component Summary	52.52
				Mental Component Summary	45.84
				In general, would you say your health is:	Excellent

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1047 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1048 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1049 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 8	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	58.52
				Physical Component Summary	53.89
				Mental Component Summary	41.41
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1050 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1051 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1052 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 9	Global Health Score	57.94
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	52.92
				Mental Component Summary	41.98
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1053 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1054 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1055 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 10	Global Health Score	54.75
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	50.32
				Mental Component Summary	40.48
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1056 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1057 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1058 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 11	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	56.15
				Physical Component Summary	54.32
				Mental Component Summary	39.75
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1059 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1060 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1061 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	21.49
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	29.35
				Mental Health Score	45.90
				Vitality Score	44.32
				Physical Component Summary	38.24
				Mental Component Summary	39.87
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1063 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1064 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	49.01
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1065 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	48.75
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	45.90
				Vitality Score	56.15
				Physical Component Summary	46.46
				Mental Component Summary	40.35
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1067 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	49.01
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	35.03
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	51.71
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1068 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	45.90
				Vitality Score	46.69
				Physical Component Summary	48.01
				Mental Component Summary	35.70
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1069 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1070 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	45.82
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	46.48
				Mental Health Score	43.63
				Vitality Score	46.69

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1071 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	46.12
				Mental Component Summary	35.03
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1072 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1073 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
				Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	41.36
				Vitality Score	51.42
				Physical Component Summary	50.90
				Mental Component Summary	35.51

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1074 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1075 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1076 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	45.82
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	41.77
				Mental Health Score	41.36
				Vitality Score	51.42
				Physical Component Summary	45.22
				Mental Component Summary	36.96
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1077 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1078 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1079 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	41.77
				Mental Health Score	43.63
				Vitality Score	53.79
				Physical Component Summary	46.51
				Mental Component Summary	36.63
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1080 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1081 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1082 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	45.82
				Reported Health Transition	2.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	41.77
				Mental Health Score	45.90
				Vitality Score	46.69
				Physical Component Summary	43.23
				Mental Component Summary	37.08
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1084 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1085 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 10	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	41.77
				Mental Health Score	50.44
				Vitality Score	49.05
				Physical Component Summary	45.23
				Mental Component Summary	40.26
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1086 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1087 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1088 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	44.56
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	37.48
				Mental Health Score	43.63
				Vitality Score	46.69
				Physical Component Summary	39.61
				Mental Component Summary	38.27
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1089 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1090 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1091 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	47.42
				Reported Health Transition	1.00
				Physical Functioning Score	21.49
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	19.14
				Bodily Pain Score	25.07
				Mental Health Score	27.73
				Vitality Score	27.75
				Physical Component Summary	34.59
				Mental Component Summary	29.53
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1093 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1094 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A good bit of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 3a	Global Health Score	51.56
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1095 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	48.53
				Mental Component Summary	42.42
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1096 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1097 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	62.75

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1098 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	51.46
				Mental Component Summary	39.88
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1100 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	54.75
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	58.52

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1101 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	49.53
				Mental Component Summary	44.04
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1102 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1103 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	47.42
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	51.75
				Mental Component Summary	40.64

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1104 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1105 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1106 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	47.42
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	49.05
				Physical Component Summary	50.59
				Mental Component Summary	39.37
				In general, would you say your health is:	Very good

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1108 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1109 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	48.75
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	47.80
				Mental Component Summary	42.89
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1110 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1111 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1112 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	44.23
				Reported Health Transition	3.00
				Physical Functioning Score	46.66
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	44.92
				Mental Component Summary	43.50
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1113 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1114 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1115 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 10	Global Health Score	45.82
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	50.26
				Mental Component Summary	39.96
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1116 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1117 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1118 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 11	Global Health Score	42.63
				Reported Health Transition	2.00
				Physical Functioning Score	42.46
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	47.33
				Mental Health Score	
				Vitality Score	
				Physical Component Summary	
				Mental Component Summary	
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1119 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1120 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 11	<p>During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?</p> <p>For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?</p> <p>For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?</p> <p>How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?</p> <p>For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?</p> <p>For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?</p> <p>For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?</p> <p>For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?</p> <p>For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?</p> <p>For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?</p> <p>During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?</p> <p>How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people</p> <p>How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know</p>	<p>A little of the time</p> <p>Definitely false</p> <p>Mostly false</p>

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1121 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0150	ES		Baseline (Visit 2a)	Global Health Score	33.62
				Reported Health Transition	3.00
				Physical Functioning Score	40.83
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	37.48
				Mental Health Score	43.63
				Vitality Score	37.22
				Physical Component Summary	33.96
				Mental Component Summary	35.68
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1123 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0150	ES	Baseline (Visit 2a)		Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1124 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0150	ES	Baseline (Visit 2a)		For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1125 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	46.78
				Reported Health Transition	2.00
				Physical Functioning Score	25.68
				Role/Physical Score	56.24
				Role Emotional Score	
				Social Functioning Score	35.42
				Bodily Pain Score	29.35
				Mental Health Score	34.54
				Vitality Score	34.85
				Physical Component Summary	
				Mental Component Summary	
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1126 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1127 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 3a	Global Health Score	56.35
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1128 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	45.90
				Vitality Score	53.79
				Physical Component Summary	53.57
				Mental Component Summary	37.52
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1129 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1130 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1131 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	50.44
				Vitality Score	56.15
				Physical Component Summary	52.40
				Mental Component Summary	40.30
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1132 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1133 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	57.94
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	53.79

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1134 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	53.36
				Mental Component Summary	40.32
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1135 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1136 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	57.94
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	52.92
				Mental Component Summary	41.98

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1137 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1138 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1139 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	53.58
				Mental Component Summary	40.87
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1140 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1141 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1142 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 8	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	59.53
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	53.82
				Mental Component Summary	40.85
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1143 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1144 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1145 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 9	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	46.48
				Mental Health Score	50.44
				Vitality Score	49.05
				Physical Component Summary	46.76
				Mental Component Summary	38.34
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1146 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1147 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1148 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	45.90
				Vitality Score	51.42
				Physical Component Summary	54.16
				Mental Component Summary	36.49
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1149 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1150 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1151 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	53.79
				Physical Component Summary	52.47
				Mental Component Summary	37.85
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1152 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1153 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1154 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	36.17
				Role/Physical Score	37.38
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	33.63
				Mental Health Score	50.44
				Vitality Score	51.42
				Physical Component Summary	38.36
				Mental Component Summary	43.74
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1156 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1157 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	49.01
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1158 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	57.14
				Bodily Pain Score	42.19
				Mental Health Score	54.99
				Vitality Score	49.05
				Physical Component Summary	40.71
				Mental Component Summary	56.54
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1160 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 5	Global Health Score	52.36
				Reported Health Transition	5.00
				Physical Functioning Score	46.66
				Role/Physical Score	42.10
				Role Emotional Score	44.81
			Visit 5	Social Functioning Score	57.14
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1161 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 5	Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	43.34
				Mental Component Summary	52.36
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1163 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 6	Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	46.66
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	42.19
				Mental Health Score	52.72
				Vitality Score	53.79

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1164 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	46.71
				Mental Component Summary	43.03
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1165 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1166 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	38.27
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	37.48
				Mental Health Score	52.72
				Vitality Score	53.79
				Physical Component Summary	35.90
				Mental Component Summary	47.21

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1167 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1168 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1169 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	40.83
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	33.63
				Mental Health Score	50.44
				Vitality Score	56.15
				Physical Component Summary	43.78
				Mental Component Summary	43.83
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1170 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1171 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1172 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 9	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	47.42
				Reported Health Transition	3.00
				Physical Functioning Score	38.27
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	33.20
				Mental Health Score	45.90
				Vitality Score	39.59
				Physical Component Summary	41.93
				Mental Component Summary	36.98
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1174 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1175 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 10	Global Health Score	45.82
				Reported Health Transition	2.00
				Physical Functioning Score	44.56
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	37.48
				Mental Health Score	43.63
				Vitality Score	41.95
				Physical Component Summary	43.77
				Mental Component Summary	31.09
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1177 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1178 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 11	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	42.46
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	37.48
				Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	41.72
				Mental Component Summary	43.62
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1179 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1180 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1181 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	45.82
				Reported Health Transition	1.00
				Physical Functioning Score	23.58
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	29.35
				Mental Health Score	48.17
				Vitality Score	44.32
				Physical Component Summary	31.28
				Mental Component Summary	42.38
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1183 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1184 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	52.20
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1185 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	46.66
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	42.19
				Mental Health Score	52.72
				Vitality Score	58.52
				Physical Component Summary	51.02
				Mental Component Summary	42.45
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1186 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1187 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	50.61
				Reported Health Transition	2.00
				Physical Functioning Score	42.46
				Role/Physical Score	56.24
				Role Emotional Score	44.81
			Visit 4	Social Functioning Score	46.28
				Bodily Pain Score	21.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1188 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	39.08
				Vitality Score	41.95
				Physical Component Summary	40.68
				Mental Component Summary	41.21
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1190 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	47.42
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	45.90
				Vitality Score	51.42

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1191 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	48.21
				Mental Component Summary	38.25
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1192 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1193 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	50.61
				Reported Health Transition	2.00
				Physical Functioning Score	44.56
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	41.77
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	42.12
				Mental Component Summary	43.60

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1194 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1196 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
				Global Health Score	52.20
				Reported Health Transition	4.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	41.77
				Mental Health Score	57.26
				Vitality Score	56.15
				Physical Component Summary	41.66
				Mental Component Summary	46.67
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1197 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1198 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1199 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	47.42
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	56.15
				Physical Component Summary	55.46
				Mental Component Summary	35.76
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1201 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1202 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 9	Global Health Score	53.16
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	57.26
				Vitality Score	58.52
				Physical Component Summary	47.34
				Mental Component Summary	45.35
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1203 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1204 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1205 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	41.04
				Reported Health Transition	2.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	46.48
				Mental Health Score	57.26
				Vitality Score	49.05
				Physical Component Summary	41.98
				Mental Component Summary	42.29
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1206 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1207 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1208 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic ES/SAF/FAS	Visit 10		How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
		Visit 11		Global Health Score	53.16
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.05
				Mental Health Score	45.90
				Vitality Score	46.69
				Physical Component Summary	47.27
				Mental Component Summary	37.52
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1209 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1210 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1211 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	52.20
				Reported Health Transition	1.00
				Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	57.14
				Bodily Pain Score	29.35
				Mental Health Score	45.90
				Vitality Score	44.32
				Physical Component Summary	37.52
				Mental Component Summary	53.18
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1213 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1214 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	55.39
				Reported Health Transition	4.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1215 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	55.05
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	53.88
				Mental Component Summary	41.63
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1216 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1217 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 4	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1218 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	44.91
				Mental Component Summary	42.40
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1220 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	56.98
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	60.89

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1221 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	51.82
				Mental Component Summary	45.32
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1222 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1223 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	51.56
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	60.89
				Physical Component Summary	51.97
				Mental Component Summary	42.09

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1224 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1225 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1226 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	56.35
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	63.25
				Physical Component Summary	51.73
				Mental Component Summary	45.89
				In general, would you say your health is:	Excellent

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1227 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1228 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1229 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	63.25
				Physical Component Summary	52.52
				Mental Component Summary	45.84
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1230 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1231 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1232 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 9	Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	63.25
				Physical Component Summary	52.78
				Mental Component Summary	44.75
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1234 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1235 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 10	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	56.15
				Physical Component Summary	50.49
				Mental Component Summary	44.28
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1236 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1237 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1238 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 11	Global Health Score	56.35
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	53.79
				Physical Component Summary	51.96
				Mental Component Summary	42.55
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1239 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1240 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1241 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0202	NDisc basic	ES/SAF	Baseline (Visit 2a)	Global Health Score	46.78
				Reported Health Transition	3.00
				Physical Functioning Score	15.19
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	32.71
				Mental Component Summary	49.59
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1243 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0202	NDisc basic	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1244 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0202	NDisc basic ES/SAF		Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 3a	Global Health Score	58.58
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1245 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0202	NDisc basic	ES/SAF	Visit 3a	Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	52.72
				Vitality Score	54.58
				Physical Component Summary	47.48
				Mental Component Summary	42.56
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1246 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0202	NDisc basic	ES/SAF	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1247 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0202	NDisc basic	ES/SAF	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1248 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	53.79
				Reported Health Transition	2.00
				Physical Functioning Score	31.97
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	29.35
				Mental Health Score	25.45
				Vitality Score	37.22
				Physical Component Summary	44.12
				Mental Component Summary	26.75
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1249 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1250 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	52.20
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1251 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	46.66
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	62.75
				Mental Health Score	43.63
				Vitality Score	53.79
				Physical Component Summary	59.46
				Mental Component Summary	33.46
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1252 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1253 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	49.01
				Reported Health Transition	2.00
				Physical Functioning Score	34.07
				Role/Physical Score	56.24
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	37.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1254 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	39.08
				Vitality Score	51.42
				Physical Component Summary	46.20
				Mental Component Summary	37.56
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1255 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1256 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	38.27
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	42.19
			Visit 5	Mental Health Score	48.17
				Vitality Score	56.15

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1257 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	49.19
				Mental Component Summary	41.57
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1258 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1259 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	2.00
				Physical Functioning Score	52.95
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	43.63
				Vitality Score	46.69
				Physical Component Summary	50.89
				Mental Component Summary	35.50

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1260 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1262 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	49.01
				Reported Health Transition	2.00
				Physical Functioning Score	48.75
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	41.77
				Mental Health Score	48.17
				Vitality Score	53.79
				Physical Component Summary	51.85
				Mental Component Summary	38.74
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1263 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1264 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1265 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 8	Global Health Score	50.61
				Reported Health Transition	2.00
				Physical Functioning Score	46.66
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	37.48
				Mental Health Score	32.27
				Vitality Score	49.05
				Physical Component Summary	53.37
				Mental Component Summary	30.77
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1267 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1268 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	47.42
				Reported Health Transition	2.00
				Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	35.42
				Bodily Pain Score	37.48
				Mental Health Score	30.00
				Vitality Score	53.79
				Physical Component Summary	48.44
				Mental Component Summary	34.63
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1270 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1271 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 10	Global Health Score	44.23
				Reported Health Transition	3.00
				Physical Functioning Score	46.66
				Role/Physical Score	56.24
				Role Emotional Score	34.27
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	41.36
				Vitality Score	46.69
				Physical Component Summary	47.80
				Mental Component Summary	34.93
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1272 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1273 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1274 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 11	Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	48.17
				Vitality Score	53.79
				Physical Component Summary	49.34
				Mental Component Summary	38.26
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1275 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1276 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1277 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0204	NDisc basic	ES/SAF	Baseline (Visit 2a)	Global Health Score	49.01
				Reported Health Transition	2.00
				Physical Functioning Score	38.27
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	33.63
				Mental Health Score	39.08
				Vitality Score	39.59
				Physical Component Summary	46.41
				Mental Component Summary	34.19
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1279 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0204	NDisc basic	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1280 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0204	NDisc basic	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1281 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	48.37
				Reported Health Transition	1.00
				Physical Functioning Score	19.39
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	35.42
				Bodily Pain Score	25.07
				Mental Health Score	34.54
				Vitality Score	34.85
				Physical Component Summary	32.51
				Mental Component Summary	39.36
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1282 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1283 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	55.39
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1284 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	44.56
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	57.26
				Vitality Score	56.15
				Physical Component Summary	50.36
				Mental Component Summary	44.49
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1285 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1286 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	48.75
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1287 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	59.53
				Vitality Score	63.25
				Physical Component Summary	44.39
				Mental Component Summary	48.91
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1289 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	54.18
				Mental Health Score	59.53
				Vitality Score	65.62

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1290 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	47.95
				Mental Component Summary	47.77
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1291 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1292 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	65.62
				Physical Component Summary	50.67
				Mental Component Summary	46.94

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1293 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1294 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1295 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	63.25
				Physical Component Summary	50.11
				Mental Component Summary	46.84
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1296 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1297 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1298 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	65.62
				Physical Component Summary	48.19
				Mental Component Summary	47.52
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1299 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1300 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1301 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 9	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	63.25
				Physical Component Summary	50.30
				Mental Component Summary	45.33
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1303 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1304 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 10	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	50.76
				Mental Health Score	59.53
				Vitality Score	60.89
				Physical Component Summary	46.72
				Mental Component Summary	46.99
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1305 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1306 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1307 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	59.53
				Vitality Score	63.25
				Physical Component Summary	47.53
				Mental Component Summary	47.53
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1308 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1309 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1310 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	43.59
				Reported Health Transition	2.00
				Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	35.42
				Bodily Pain Score	29.35
				Mental Health Score	32.27
				Vitality Score	34.85
				Physical Component Summary	40.29
				Mental Component Summary	34.05
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1312 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1313 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 3a	Global Health Score	50.61
				Reported Health Transition	4.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1314 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	34.54
				Vitality Score	32.49
				Physical Component Summary	54.44
				Mental Component Summary	24.67
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1315 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1316 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	46.78
				Reported Health Transition	4.00
				Physical Functioning Score	42.46
				Role/Physical Score	56.24
				Role Emotional Score	34.27
			Visit 4	Social Functioning Score	35.42
				Bodily Pain Score	37.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1317 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	25.45
				Vitality Score	39.59
				Physical Component Summary	50.01
				Mental Component Summary	25.00
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1318 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1319 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	49.01
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	46.48
				Mental Health Score	34.54
				Vitality Score	41.95

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1320 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	50.95
				Mental Component Summary	37.73
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1321 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1322 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	47.42
				Reported Health Transition	4.00
				Physical Functioning Score	50.85
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	51.61
				Mental Health Score	41.36
				Vitality Score	41.95
				Physical Component Summary	49.26
				Mental Component Summary	30.92

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1323 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1324 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1325 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 7	Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	48.75
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	41.36
				Vitality Score	49.05
				Physical Component Summary	46.84
				Mental Component Summary	35.36
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1326 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1327 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1328 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	47.42
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	50.44
				Vitality Score	51.42
				Physical Component Summary	46.78
				Mental Component Summary	38.93
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1330 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1331 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	44.23
				Reported Health Transition	3.00
				Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	34.27
				Social Functioning Score	35.42
				Bodily Pain Score	37.48
				Mental Health Score	32.27
				Vitality Score	39.59
				Physical Component Summary	48.75
				Mental Component Summary	27.86
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1333 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1334 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 11	Global Health Score	47.42
				Reported Health Transition	4.00
				Physical Functioning Score	50.85
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	41.36
				Vitality Score	41.95
				Physical Component Summary	47.63
				Mental Component Summary	31.42
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1335 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1336 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1337 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0207	ES		Baseline (Visit 2a)	Global Health Score	42.00
				Reported Health Transition	2.00
				Physical Functioning Score	23.58
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	19.14
				Bodily Pain Score	19.93
				Mental Health Score	20.91
				Vitality Score	20.65
				Physical Component Summary	31.77
				Mental Component Summary	29.23
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1339 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0207	ES	Baseline (Visit 2a)		Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1340 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0207	ES	Baseline (Visit 2a)		For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1341 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	45.18
				Reported Health Transition	5.00
				Physical Functioning Score	42.46
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	33.20
				Mental Health Score	27.73
				Vitality Score	39.59
				Physical Component Summary	47.25
				Mental Component Summary	24.30
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1342 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1343 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	49.01
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1344 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	55.90
				Mental Health Score	36.81
				Vitality Score	41.95
				Physical Component Summary	49.49
				Mental Component Summary	30.61
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1345 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1346 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 4	Global Health Score	45.82
				Reported Health Transition	5.00
				Physical Functioning Score	44.56
				Role/Physical Score	42.10
				Role Emotional Score	44.81
			Visit 4	Social Functioning Score	46.28
				Bodily Pain Score	42.19

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1347 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	27.73
				Vitality Score	37.22
				Physical Component Summary	44.51
				Mental Component Summary	33.85
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1348 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1349 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	38.81
				Reported Health Transition	2.00
				Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	35.42
				Bodily Pain Score	29.35
				Mental Health Score	23.18
				Vitality Score	32.49

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1350 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	41.04
				Mental Component Summary	29.16
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1351 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1352 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
				Global Health Score	47.42
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	42.10
				Role Emotional Score	34.27
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	39.08
				Vitality Score	46.69
				Physical Component Summary	49.61
				Mental Component Summary	34.65

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1353 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1354 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1355 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 7	Global Health Score	49.01
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	55.90
				Mental Health Score	39.08
				Vitality Score	41.95
				Physical Component Summary	52.37
				Mental Component Summary	30.36
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1356 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1357 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1358 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 8	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	45.82
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	62.75
				Mental Health Score	45.90
				Vitality Score	46.69
				Physical Component Summary	54.86
				Mental Component Summary	33.29
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1360 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1361 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 9	Global Health Score	44.23
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	36.81
				Vitality Score	41.95
				Physical Component Summary	46.90
				Mental Component Summary	32.56
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1363 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1364 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 10	Global Health Score	41.04
				Reported Health Transition	3.00
				Physical Functioning Score	46.66
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	39.08
				Vitality Score	34.85
				Physical Component Summary	47.04
				Mental Component Summary	28.84
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1365 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1366 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1367 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 11	Global Health Score	41.04
				Reported Health Transition	3.00
				Physical Functioning Score	48.75
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	42.19
				Mental Health Score	39.08
				Vitality Score	34.85
				Physical Component Summary	44.08
				Mental Component Summary	29.65
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1368 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1369 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1370 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	48.37
				Reported Health Transition	2.00
				Physical Functioning Score	42.46
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	33.20
				Mental Health Score	41.36
				Vitality Score	39.59
				Physical Component Summary	47.39
				Mental Component Summary	34.38
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1372 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1373 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	55.39
				Reported Health Transition	4.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1374 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	48.75
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	52.72
				Vitality Score	44.32
				Physical Component Summary	53.66
				Mental Component Summary	38.16
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1375 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1376 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	48.75
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.05

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1377 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	48.17
				Vitality Score	51.42
				Physical Component Summary	46.08
				Mental Component Summary	40.36
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1379 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	54.99
				Vitality Score	56.15

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1380 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	51.14
				Mental Component Summary	42.38
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1381 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1382 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	56.15
				Physical Component Summary	51.60
				Mental Component Summary	43.70

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1383 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1385 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	51.42
				Physical Component Summary	52.26
				Mental Component Summary	39.18
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1386 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1387 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1388 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	58.52
				Physical Component Summary	53.14
				Mental Component Summary	42.89
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1389 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1390 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1391 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	52.72
				Vitality Score	49.05
				Physical Component Summary	52.78
				Mental Component Summary	39.06
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1393 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1394 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	51.36
				Mental Component Summary	40.31
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1395 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1396 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1397 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 11	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	51.42
				Physical Component Summary	52.36
				Mental Component Summary	38.75
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1398 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1399 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1400 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0210	ES	Baseline	(Visit 2a)	Global Health Score	40.40
				Reported Health Transition	1.00
				Physical Functioning Score	27.78
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	29.35
				Mental Health Score	36.81
				Vitality Score	37.22
				Physical Component Summary	39.05
				Mental Component Summary	29.65
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1402 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0210	ES	Baseline (Visit 2a)		Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1403 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0210	ES	Baseline (Visit 2a)		For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1404 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0211	NDisc basic	ES/SAF	Baseline (Visit 2a)	Global Health Score	55.39
				Reported Health Transition	2.00
				Physical Functioning Score	31.97
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	29.35
				Mental Health Score	23.18
				Vitality Score	39.59
				Physical Component Summary	45.12
				Mental Component Summary	24.72
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1405 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0211	NDisc basic	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1406 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0211	NDisc basic ES/SAF		Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	47.42
				Reported Health Transition	4.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1407 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0211	NDisc basic	ES/SAF	Visit 3a	Physical Functioning Score	46.66
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	37.48
				Mental Health Score	27.73
				Vitality Score	34.85
				Physical Component Summary	50.85
				Mental Component Summary	20.31
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1408 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0211	NDisc basic ES/SAF		Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1409 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0211	NDisc basic	ES/SAF	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1410 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	34.07
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	33.20
				Mental Health Score	36.81
				Vitality Score	30.12
				Physical Component Summary	46.04
				Mental Component Summary	27.41
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1411 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1412 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	49.01
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1413 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	40.36
				Role/Physical Score	49.17
				Role Emotional Score	34.27
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	52.72
				Vitality Score	49.05
				Physical Component Summary	44.14
				Mental Component Summary	46.75
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1415 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	45.82
				Reported Health Transition	5.00
				Physical Functioning Score	44.56
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	37.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1416 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 5	Mental Health Score	43.63
				Vitality Score	46.69
				Physical Component Summary	38.77
				Mental Component Summary	39.78
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1418 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 6	Global Health Score	49.01
				Reported Health Transition	5.00
				Physical Functioning Score	46.66
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	50.44
				Vitality Score	53.79

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1419 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	42.02
				Mental Component Summary	43.35
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1420 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1421 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	53.79
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	41.77
				Mental Health Score	50.44
				Vitality Score	44.32
				Physical Component Summary	44.11
				Mental Component Summary	40.06

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1422 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1424 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	42.46
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.05
				Mental Health Score	45.90
				Vitality Score	49.05
				Physical Component Summary	42.16
				Mental Component Summary	40.96
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1425 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1426 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1427 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 9	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	48.75
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	48.17
				Vitality Score	53.79
				Physical Component Summary	44.60
				Mental Component Summary	41.69
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1429 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1430 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	46.78
				Reported Health Transition	2.00
				Physical Functioning Score	46.66
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	37.48
				Mental Health Score	48.17
				Vitality Score	51.42
				Physical Component Summary	39.04
				Mental Component Summary	42.60
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1432 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1433 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	47.42
				Reported Health Transition	3.00
				Physical Functioning Score	48.75
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.05
				Mental Health Score	43.63
				Vitality Score	56.15
				Physical Component Summary	43.94
				Mental Component Summary	40.18
		In general, would you say your health is:	Good		
		Compared to one year ago, how would you rate your health in general now?	About the same as one year ago		
		Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little		
		Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little		
		Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1434 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1435 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1436 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0213	NDisc plus	ES/SAF	Baseline (Visit 2a)	Global Health Score	53.79
				Reported Health Transition	1.00
				Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	25.07
				Mental Health Score	25.45
				Vitality Score	34.85
				Physical Component Summary	40.96
				Mental Component Summary	35.57
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1438 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0213	NDisc plus	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1439 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0213	NDisc plus	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1440 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	46.78
				Reported Health Transition	2.00
				Physical Functioning Score	36.17
				Role/Physical Score	49.17
				Role Emotional Score	44.81
				Social Functioning Score	40.85
				Bodily Pain Score	33.63
				Mental Health Score	25.45
				Vitality Score	37.22
				Physical Component Summary	41.50
				Mental Component Summary	33.16
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1441 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1442 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 3a	Global Health Score	49.01
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1443 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	52.95
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	43.63
				Vitality Score	39.59
				Physical Component Summary	50.83
				Mental Component Summary	30.59
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1444 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1445 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 4	Global Health Score	44.23
				Reported Health Transition	4.00
				Physical Functioning Score	21.49
				Role/Physical Score	27.95
				Role Emotional Score	34.27
			Visit 4	Social Functioning Score	51.71
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1446 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	45.90
				Vitality Score	46.69
				Physical Component Summary	30.60
				Mental Component Summary	47.95
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1448 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 6	Global Health Score	34.02
				Reported Health Transition	4.00
				Physical Functioning Score	36.17
				Role/Physical Score	42.10
				Role Emotional Score	44.81
				Social Functioning Score	46.28
				Bodily Pain Score	29.35
				Mental Health Score	41.36
				Vitality Score	35.64

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1449 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 6	Physical Component Summary	30.88
				Mental Component Summary	43.47
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1450 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1451 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
			Visit 7	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
				Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	46.48
				Mental Health Score	54.99
				Vitality Score	46.69
				Physical Component Summary	44.80
				Mental Component Summary	40.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1452 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1453 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1454 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 9	Global Health Score	56.98
				Reported Health Transition	3.00
				Physical Functioning Score	54.81
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	51.70
				Mental Component Summary	42.53
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1455 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 9	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1456 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 9	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1457 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	51.56
				Reported Health Transition	1.00
				Physical Functioning Score	46.66
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	29.35
				Mental Health Score	30.00
				Vitality Score	39.59
				Physical Component Summary	51.33
				Mental Component Summary	25.30
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1459 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1460 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 11	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0215	ES	Baseline	(Visit 2a)	Global Health Score	38.81
				Reported Health Transition	2.00
				Physical Functioning Score	29.88
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	37.48
				Mental Health Score	36.81
				Vitality Score	37.22
				Physical Component Summary	36.06
				Mental Component Summary	42.12
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1462 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0215	ES	Baseline	(Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1463 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0215	ES	Baseline (Visit 2a)		For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1464 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0216	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	45.82
				Reported Health Transition	3.00
				Physical Functioning Score	25.68
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	29.35
				Mental Health Score	36.81
				Vitality Score	32.49
				Physical Component Summary	34.29
				Mental Component Summary	35.06
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1465 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0216	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1466 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0216	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	47.42
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1467 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0216	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	40.36
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	41.36
				Vitality Score	44.32
				Physical Component Summary	43.17
				Mental Component Summary	37.31
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0216	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1469 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0216	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	42.63
				Reported Health Transition	2.00
				Physical Functioning Score	40.36
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	37.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1470 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0216	NDisc plus	ES/SAF/FAS	Visit 5	Mental Health Score	48.17
				Vitality Score	51.42
				Physical Component Summary	40.30
				Mental Component Summary	42.37
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0216	NDisc plus	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1472 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0216	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1473 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	47.42
				Reported Health Transition	1.00
				Physical Functioning Score	23.58
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	19.14
				Bodily Pain Score	25.07
				Mental Health Score	36.81
				Vitality Score	34.85
				Physical Component Summary	31.65
				Mental Component Summary	39.71
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1474 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1475 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 4	Global Health Score	50.61
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1476 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	50.44
				Vitality Score	56.15
				Physical Component Summary	47.25
				Mental Component Summary	42.00
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1477 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1478 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1479 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 5	Mental Health Score	50.44
				Vitality Score	53.79
				Physical Component Summary	51.14
				Mental Component Summary	39.82
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1481 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 6	Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	56.15

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1482 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	51.60
				Mental Component Summary	40.35
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1483 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1484 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	53.79
				Physical Component Summary	51.92
				Mental Component Summary	40.41

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1485 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1487 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	51.42
				Physical Component Summary	51.56
				Mental Component Summary	38.80
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1488 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1489 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1490 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	49.05
				Physical Component Summary	52.29
				Mental Component Summary	38.19
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1491 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1492 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1493 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
			Visit 10	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	45.90
				Vitality Score	41.95
				Physical Component Summary	47.87
				Mental Component Summary	35.93
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1495 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1496 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 11	Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	49.05
				Physical Component Summary	50.10
				Mental Component Summary	39.83
		In general, would you say your health is:	Good		
		Compared to one year ago, how would you rate your health in general now?	About the same as one year ago		
		Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little		
		Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all		
		Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1497 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1498 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1499 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0218	NDisc basic	ES/SAF	Baseline (Visit 2a)	Global Health Score	48.37
				Reported Health Transition	1.00
				Physical Functioning Score	29.88
				Role/Physical Score	49.17
				Role Emotional Score	34.27
				Social Functioning Score	46.28
				Bodily Pain Score	29.35
				Mental Health Score	45.90
				Vitality Score	44.32
				Physical Component Summary	35.54
				Mental Component Summary	43.49
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1501 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0218	NDisc basic	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1502 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0218	NDisc basic	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1503 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	47.42
				Reported Health Transition	1.00
				Physical Functioning Score	38.27
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	25.07
				Mental Health Score	27.73
				Vitality Score	30.12
				Physical Component Summary	39.62
				Mental Component Summary	35.18
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1504 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1505 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 3a	Global Health Score	42.63
				Reported Health Transition	4.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1506 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	46.66
				Role/Physical Score	56.24
				Role Emotional Score	34.27
				Social Functioning Score	46.28
				Bodily Pain Score	37.48
				Mental Health Score	41.36
				Vitality Score	39.59
				Physical Component Summary	47.16
				Mental Component Summary	34.74
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1507 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1508 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 4	Global Health Score	41.04
				Reported Health Transition	4.00
				Physical Functioning Score	46.66
				Role/Physical Score	49.17
				Role Emotional Score	44.81
			Visit 4	Social Functioning Score	35.42
				Bodily Pain Score	42.19

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1509 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	25.45
				Vitality Score	41.95
				Physical Component Summary	47.41
				Mental Component Summary	29.66
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1510 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1511 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	44.23
				Reported Health Transition	2.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	30.00
				Vitality Score	34.85

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1512 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	49.56
				Mental Component Summary	27.16
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1513 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1514 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
				Global Health Score	44.23
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	42.10
				Role Emotional Score	44.81
				Social Functioning Score	51.71
				Bodily Pain Score	46.48
				Mental Health Score	36.81
				Vitality Score	37.22
				Physical Component Summary	47.87
				Mental Component Summary	36.92

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1515 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1516 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1517 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 7	Global Health Score	45.82
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	46.48
				Mental Health Score	34.54
				Vitality Score	44.32
				Physical Component Summary	49.65
				Mental Component Summary	29.67
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1518 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1519 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1520 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	45.82
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	36.81
				Vitality Score	37.22
				Physical Component Summary	52.48
				Mental Component Summary	29.37
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1522 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1523 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	42.63
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	35.03
				Role Emotional Score	44.81
				Social Functioning Score	40.85
				Bodily Pain Score	46.48
				Mental Health Score	30.00
				Vitality Score	37.22
				Physical Component Summary	45.69
				Mental Component Summary	32.07
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1525 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1526 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 10	Global Health Score	45.82
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	49.17
				Role Emotional Score	34.27
				Social Functioning Score	40.85
				Bodily Pain Score	41.77
				Mental Health Score	36.81
				Vitality Score	39.59
				Physical Component Summary	50.54
				Mental Component Summary	30.03
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1527 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1528 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1529 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	62.75
				Mental Health Score	20.91
				Vitality Score	32.49
				Physical Component Summary	56.81
				Mental Component Summary	14.64
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1530 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1531 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1532 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	38.81
				Reported Health Transition	1.00
				Physical Functioning Score	17.29
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	30.00
				Bodily Pain Score	19.93
				Mental Health Score	16.37
				Vitality Score	20.65
				Physical Component Summary	29.22
				Mental Component Summary	31.43
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1534 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1535 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	All of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 4	Global Health Score	49.01
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1536 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	42.19
				Mental Health Score	44.20
				Vitality Score	34.85
				Physical Component Summary	41.03
				Mental Component Summary	44.55
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1538 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	
			Visit 5	Global Health Score	45.82
				Reported Health Transition	5.00
				Physical Functioning Score	36.17
				Role/Physical Score	42.10
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	41.77

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1539 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 5	Mental Health Score	27.73
				Vitality Score	32.49
				Physical Component Summary	38.70
				Mental Component Summary	37.82
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1541 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 6	Global Health Score	45.82
				Reported Health Transition	5.00
				Physical Functioning Score	38.27
				Role/Physical Score	42.10
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	42.19
				Mental Health Score	25.45
				Vitality Score	23.02

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1542 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	39.95
				Mental Component Summary	33.97
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1543 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
					No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1544 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	45.82
				Reported Health Transition	5.00
				Physical Functioning Score	48.75
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	23.18
				Vitality Score	27.75
				Physical Component Summary	48.51
				Mental Component Summary	30.28

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1545 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1547 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 8	Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	38.27
				Role/Physical Score	27.95
				Role Emotional Score	44.81
				Social Functioning Score	40.85
				Bodily Pain Score	46.48
				Mental Health Score	30.00
				Vitality Score	30.12
				Physical Component Summary	38.76
				Mental Component Summary	34.52
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1548 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1549 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1550 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	40.36
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	46.48
				Mental Health Score	23.18
				Vitality Score	27.75
				Physical Component Summary	44.78
				Mental Component Summary	19.59
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1551 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1552 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1553 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	40.36
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	33.63
				Mental Health Score	23.18
				Vitality Score	27.75
				Physical Component Summary	40.62
				Mental Component Summary	23.76
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1555 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1556 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	37.21
				Reported Health Transition	2.00
				Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	30.00
				Bodily Pain Score	33.20
				Mental Health Score	18.64
				Vitality Score	27.75
				Physical Component Summary	40.75
				Mental Component Summary	28.60
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1558 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1559 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0221	NDisc plus	ES/SAF	Baseline (Visit 2a)	Global Health Score	49.97
				Reported Health Transition	1.00
				Physical Functioning Score	21.49
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	24.21
				Mental Health Score	48.17
				Vitality Score	32.49
				Physical Component Summary	34.46
				Mental Component Summary	37.31
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1561 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0221	NDisc plus	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1562 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0221	NDisc plus	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1563 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0222	NDisc plus	ES/SAF	Baseline (Visit 2a)	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	15.19
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	24.57
				Bodily Pain Score	19.93
				Mental Health Score	45.90
				Vitality Score	41.95
				Physical Component Summary	31.48
				Mental Component Summary	35.91
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1564 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0222	NDisc plus	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1565 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0222	NDisc plus	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1566 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	40.40
				Reported Health Transition	1.00
				Physical Functioning Score	24.52
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	13.71
				Bodily Pain Score	25.07
				Mental Health Score	18.64
				Vitality Score	20.65
				Physical Component Summary	33.94
				Mental Component Summary	25.97
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1567 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1568 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	All of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 3a	Global Health Score	52.20
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1569 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	24.57
				Bodily Pain Score	51.61
				Mental Health Score	16.37
				Vitality Score	32.49
				Physical Component Summary	52.79
				Mental Component Summary	24.16
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1570 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1571 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 4	Global Health Score	45.82
				Reported Health Transition	4.00
				Physical Functioning Score	38.27
				Role/Physical Score	56.24
				Role Emotional Score	55.34
			Visit 4	Social Functioning Score	35.42
				Bodily Pain Score	42.19

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1572 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	16.37
				Vitality Score	25.39
				Physical Component Summary	47.03
				Mental Component Summary	26.91
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1573 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1574 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	48.75
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	55.90
				Mental Health Score	41.36
				Vitality Score	44.32

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1575 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	51.75
				Mental Component Summary	32.88
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1576 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1577 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	47.42
				Reported Health Transition	5.00
				Physical Functioning Score	48.75
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	55.90
				Mental Health Score	36.81
				Vitality Score	41.95
				Physical Component Summary	48.29
				Mental Component Summary	28.20

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1578 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1580 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 7	Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	44.81
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	27.73
				Vitality Score	37.22
				Physical Component Summary	48.04
				Mental Component Summary	34.08
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1581 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1582 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1583 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 8	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	46.78
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	41.36
				Vitality Score	41.95
				Physical Component Summary	51.85
				Mental Component Summary	32.68
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1584 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1585 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1586 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
			Visit 8	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	
			Visit 9	Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	
				Social Functioning Score	46.28
				Bodily Pain Score	37.06
				Mental Health Score	27.73
				Vitality Score	27.75
				Physical Component Summary	
				Mental Component Summary	
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1588 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 9	<p>past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual</p> <p>During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?</p> <p>How much bodily pain have you had during the past 4 weeks?</p> <p>During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?</p> <p>For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?</p> <p>For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?</p> <p>How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?</p> <p>For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?</p> <p>For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?</p> <p>For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?</p> <p>For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?</p> <p>For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?</p> <p>For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?</p>	<p>Not at all</p> <p>Some of the time</p> <p>A little of the time</p> <p>A good bit of the time</p> <p>A little of the time</p> <p>A little of the time</p> <p>A good bit of the time</p> <p>Most of the time</p> <p>Some of the time</p> <p>All of the time</p>

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1589 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	47.42
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	51.61
				Mental Health Score	25.45
				Vitality Score	30.12
				Physical Component Summary	45.73
				Mental Component Summary	31.12
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1590 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1591 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1592 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 11	Global Health Score	47.42
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	55.90
				Mental Health Score	30.00
				Vitality Score	34.85
				Physical Component Summary	47.08
				Mental Component Summary	35.00
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1593 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1594 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1595 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0224	NDisc plus	ES/SAF	Baseline (Visit 2a)	Global Health Score	52.20
				Reported Health Transition	1.00
				Physical Functioning Score	27.78
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	33.63
				Mental Health Score	32.27
				Vitality Score	39.59
				Physical Component Summary	39.34
				Mental Component Summary	33.52
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1597 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0224	NDisc plus	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1598 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0224	NDisc plus	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1599 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	48.37
				Reported Health Transition	1.00
				Physical Functioning Score	31.97
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	13.71
				Bodily Pain Score	19.93
				Mental Health Score	27.73
				Vitality Score	39.59
				Physical Component Summary	36.00
				Mental Component Summary	33.50
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1601 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	All of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 4	Global Health Score	55.39
				Reported Health Transition	4.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1602 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	37.48
				Mental Health Score	30.00
				Vitality Score	37.22
				Physical Component Summary	47.93
				Mental Component Summary	35.17
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1604 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 5	Social Functioning Score	46.28
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1605 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 5	Mental Health Score	48.17
				Vitality Score	56.15
				Physical Component Summary	48.16
				Mental Component Summary	37.87
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1607 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 6	Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	56.15

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1608 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	51.60
				Mental Component Summary	40.35
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1609 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1610 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	54.75
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	53.79
				Physical Component Summary	52.06
				Mental Component Summary	41.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1611 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1612 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1613 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	53.16
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	51.42
				Physical Component Summary	52.60
				Mental Component Summary	38.74
				In general, would you say your health is:	Excellent

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1614 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1615 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1616 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	53.16
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	53.79
				Physical Component Summary	51.16
				Mental Component Summary	42.60
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1617 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1618 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1619 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	55.34
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	63.25
				Physical Component Summary	46.95
				Mental Component Summary	58.45
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1621 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1622 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 11	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	65.62
				Physical Component Summary	52.59
				Mental Component Summary	46.39
		In general, would you say your health is:	Excellent		
		Compared to one year ago, how would you rate your health in general now?	About the same as one year ago		
		Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all		
		Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all		
		Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1623 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1624 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1625 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	56.98
				Reported Health Transition	3.00
				Physical Functioning Score	27.78
				Role/Physical Score	56.24
				Role Emotional Score	
				Social Functioning Score	35.42
				Bodily Pain Score	21.00
				Mental Health Score	36.81
				Vitality Score	41.95
				Physical Component Summary	
				Mental Component Summary	
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1627 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	
				How much bodily pain have you had during the past 4 weeks?	
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1628 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 3a	Global Health Score	54.75
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1629 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	52.95
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	43.63
				Vitality Score	44.32
				Physical Component Summary	52.82
				Mental Component Summary	34.49
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1630 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1631 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1632 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	44.11
				Mental Component Summary	42.45
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1633 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1634 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	45.82
				Reported Health Transition	2.00
				Physical Functioning Score	50.15
				Role/Physical Score	27.95
				Role Emotional Score	44.81
				Social Functioning Score	57.14
				Bodily Pain Score	50.76
				Mental Health Score	43.63
				Vitality Score	46.69

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1635 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	41.31
				Mental Component Summary	46.35
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1636 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Yes
				How much bodily pain have you had during the past 4 weeks?	Yes
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Mild
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Not at all
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1637 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	45.82
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	43.63
				Vitality Score	37.22
				Physical Component Summary	50.97
				Mental Component Summary	32.68

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1638 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1640 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	47.42
				Reported Health Transition	4.00
				Physical Functioning Score	54.81
				Role/Physical Score	27.95
				Role Emotional Score	34.27
				Social Functioning Score	46.28
				Bodily Pain Score	62.75
				Mental Health Score	30.00
				Vitality Score	39.59
				Physical Component Summary	52.41
				Mental Component Summary	28.30
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1641 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much?	
				Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	
				Does your health now limit you in these activities? If so, how much?	NO, NOT limited at all
				Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	
				Does your health now limit you in these activities? If so, how much?	NO, NOT limited at all
				Lifting or carrying groceries	
				Does your health now limit you in these activities? If so, how much?	NO, NOT limited at all
				Climbing several flights of stairs	
				Does your health now limit you in these activities? If so, how much?	NO, NOT limited at all
				Climbing one flight of stairs	
				Does your health now limit you in these activities? If so, how much?	YES, limited a little
				Bending, kneeling, or stooping	
				Does your health now limit you in these activities? If so, how much?	NO, NOT limited at all
				Walking more than a mile	
				Does your health now limit you in these activities? If so, how much?	NO, NOT limited at all
				Walking several blocks	
				Does your health now limit you in these activities? If so, how much?	NO, NOT limited at all
				Walking one block	
				Does your health now limit you in these activities? If so, how much?	NO, NOT limited at all
				Bathing or dressing yourself	
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1642 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1643 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	53.79
				Physical Component Summary	52.36
				Mental Component Summary	38.93
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1645 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1646 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0604	NDisc basic	ES/SAF	Baseline (Visit 2a)	Global Health Score	43.59
				Reported Health Transition	1.00
				Physical Functioning Score	31.97
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	24.57
				Bodily Pain Score	29.35
				Mental Health Score	39.08
				Vitality Score	37.22
				Physical Component Summary	35.14
				Mental Component Summary	40.54
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1648 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0604	NDisc basic	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1649 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0604	NDisc basic	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1650 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0605	NDisc plus	ES/SAF	Baseline (Visit 2a)	Global Health Score	45.82
				Reported Health Transition	2.00
				Physical Functioning Score	46.66
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	29.35
				Mental Health Score	30.00
				Vitality Score	37.22
				Physical Component Summary	43.80
				Mental Component Summary	37.09
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1651 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0605	NDisc plus	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1652 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0605	NDisc plus	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1653 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	41.04
				Reported Health Transition	2.00
				Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	24.57
				Bodily Pain Score	37.48
				Mental Health Score	16.37
				Vitality Score	39.59
				Physical Component Summary	47.50
				Mental Component Summary	26.42
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1655 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	All of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 4	Global Health Score	37.85
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1656 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	29.88
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	24.57
				Bodily Pain Score	29.35
				Mental Health Score	18.64
				Vitality Score	27.75
				Physical Component Summary	37.06
				Mental Component Summary	28.95
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1657 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1658 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 5	Global Health Score	40.40
				Reported Health Transition	2.00
				Physical Functioning Score	25.68
				Role/Physical Score	
				Role Emotional Score	44.81
				Social Functioning Score	24.57
				Bodily Pain Score	19.93

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1659 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 5	Mental Health Score	32.27
				Vitality Score	27.75
				Physical Component Summary	
				Mental Component Summary	
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1660 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1661 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 6	Global Health Score	37.21
				Reported Health Transition	4.00
				Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	33.20
				Mental Health Score	20.91
				Vitality Score	25.39

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1662 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	40.14
				Mental Component Summary	30.61
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1663 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1664 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
				Global Health Score	34.02
				Reported Health Transition	3.00
				Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	19.14
				Bodily Pain Score	24.21
				Mental Health Score	9.55
				Vitality Score	25.39
				Physical Component Summary	40.90
				Mental Component Summary	20.67

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1665 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	All of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1667 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 8	Global Health Score	35.62
				Reported Health Transition	2.00
				Physical Functioning Score	46.66
				Role/Physical Score	49.17
				Role Emotional Score	44.81
				Social Functioning Score	13.71
				Bodily Pain Score	37.48
				Mental Health Score	16.37
				Vitality Score	20.65
				Physical Component Summary	46.12
				Mental Component Summary	14.95
				In general, would you say your health is:	Poor

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1668 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1669 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1670 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	All of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 9	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	37.21
				Reported Health Transition	2.00
				Physical Functioning Score	48.75
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	13.71
				Bodily Pain Score	25.07
				Mental Health Score	9.55
				Vitality Score	20.65
				Physical Component Summary	45.43
				Mental Component Summary	16.04
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1672 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	All of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1673 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	All of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
			Visit 10	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	35.62
				Reported Health Transition	3.00
				Physical Functioning Score	48.75
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	19.14
				Bodily Pain Score	29.35
				Mental Health Score	20.91
				Vitality Score	30.12
				Physical Component Summary	44.11
				Mental Component Summary	24.85
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1674 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1675 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1676 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 11	Global Health Score	37.85
				Reported Health Transition	3.00
				Physical Functioning Score	46.66
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	19.14
				Bodily Pain Score	41.77
				Mental Health Score	20.91
				Vitality Score	25.39
				Physical Component Summary	47.59
				Mental Component Summary	22.97
		In general, would you say your health is:	Good		
		Compared to one year ago, how would you rate your health in general now?	About the same as one year ago		
		Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot		
		Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little		
		Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1677 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1678 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1679 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	37.85
				Reported Health Transition	2.00
				Physical Functioning Score	52.95
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	37.91
				Mental Health Score	36.81
				Vitality Score	46.69
				Physical Component Summary	44.51
				Mental Component Summary	32.29
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1681 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1682 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	47.42
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1683 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	48.75
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	45.90
				Vitality Score	46.69
				Physical Component Summary	48.27
				Mental Component Summary	37.27
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1684 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1685 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	44.23
				Reported Health Transition	2.00
				Physical Functioning Score	43.16
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	37.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1686 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	39.08
				Vitality Score	51.42
				Physical Component Summary	42.95
				Mental Component Summary	43.43
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1687 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1688 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	All of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	41.04
				Reported Health Transition	3.00
				Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	57.14
				Bodily Pain Score	37.48
				Mental Health Score	36.81
				Vitality Score	39.59

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1689 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	42.75
				Mental Component Summary	45.10
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1690 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1691 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 6	Global Health Score	51.56
				Reported Health Transition	4.00
				Physical Functioning Score	42.46
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	37.48
				Mental Health Score	39.08
				Vitality Score	41.95
				Physical Component Summary	44.21
				Mental Component Summary	41.25

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1692 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1693 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1694 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	47.42
				Reported Health Transition	5.00
				Physical Functioning Score	46.66
				Role/Physical Score	49.17
				Role Emotional Score	55.34
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	39.08
				Vitality Score	41.95
				Physical Component Summary	45.17
				Mental Component Summary	46.18
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1695 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1696 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1697 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 8	Global Health Score	45.82
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	46.48
				Mental Health Score	36.81
				Vitality Score	51.42
				Physical Component Summary	51.84
				Mental Component Summary	31.57
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1699 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1700 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
			Visit 9	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	42.00
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	29.35
				Mental Health Score	39.08
				Vitality Score	38.80
				Physical Component Summary	48.61
				Mental Component Summary	31.63
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1702 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1703 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	42.00
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	46.48
				Mental Health Score	45.90
				Vitality Score	39.59
				Physical Component Summary	46.94
				Mental Component Summary	33.65
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1705 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1706 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	43.63
				Vitality Score	46.69
				Physical Component Summary	49.70
				Mental Component Summary	35.87
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1707 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1708 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1709 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0608	SC	ES/SAF	Baseline (Visit 2a)	Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	49.17
				Role Emotional Score	55.34
				Social Functioning Score	51.71
				Bodily Pain Score	24.21
				Mental Health Score	52.72
				Vitality Score	49.05
				Physical Component Summary	38.30
				Mental Component Summary	54.14
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1711 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0608	SC	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1712 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0608	SC	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1713 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0609	NDisc basic	ES/SAF	Baseline (Visit 2a)	Global Health Score	46.78
				Reported Health Transition	1.00
				Physical Functioning Score	38.27
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	25.07
				Mental Health Score	32.27
				Vitality Score	34.85
				Physical Component Summary	38.56
				Mental Component Summary	39.97
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1714 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0609	NDisc basic	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1715 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0609	NDisc basic	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1716 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	46.78
				Reported Health Transition	1.00
				Physical Functioning Score	21.49
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	19.14
				Bodily Pain Score	19.93
				Mental Health Score	27.73
				Vitality Score	37.22
				Physical Component Summary	31.04
				Mental Component Summary	36.84
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1717 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1718 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	42.63
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1719 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	33.20
				Mental Health Score	43.63
				Vitality Score	39.59
				Physical Component Summary	36.89
				Mental Component Summary	44.90
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1720 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1721 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 4	Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	35.42
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1722 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	41.36
				Vitality Score	46.69
				Physical Component Summary	51.64
				Mental Component Summary	29.37
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1724 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	49.01
				Reported Health Transition	5.00
				Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	46.48
				Mental Health Score	34.54
				Vitality Score	37.22

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1725 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	50.70
				Mental Component Summary	24.82
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1726 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1727 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	45.82
				Reported Health Transition	5.00
				Physical Functioning Score	42.46
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	54.18
				Mental Health Score	36.81
				Vitality Score	46.69
				Physical Component Summary	54.79
				Mental Component Summary	26.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1728 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1730 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
				Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	48.75
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	54.18
				Mental Health Score	52.72
				Vitality Score	49.05
				Physical Component Summary	55.45
				Mental Component Summary	38.57
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1731 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1732 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1733 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
			Visit 8	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	48.75
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	51.42
				Physical Component Summary	47.30
				Mental Component Summary	43.99
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1734 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1735 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1736 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
			Visit 11	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	50.44
				Vitality Score	51.42
				Physical Component Summary	46.15
				Mental Component Summary	41.28
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1738 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 11	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1739 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0611	ES		Baseline (Visit 2a)	Global Health Score	42.00
				Reported Health Transition	1.00
				Physical Functioning Score	21.49
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	24.57
				Bodily Pain Score	19.93
				Mental Health Score	34.54
				Vitality Score	44.32
				Physical Component Summary	34.58
				Mental Component Summary	29.64
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1741 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0611	ES	Baseline	(Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1742 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0611	ES	Baseline (Visit 2a)		For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1743 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	33.63
				Mental Health Score	50.44
				Vitality Score	39.59
				Physical Component Summary	44.36
				Mental Component Summary	35.64
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1745 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	44.23
				Reported Health Transition	4.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1746 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	44.56
				Role/Physical Score	49.17
				Role Emotional Score	34.27
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	50.44
				Vitality Score	49.05
				Physical Component Summary	46.90
				Mental Component Summary	42.80
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1748 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 4	Global Health Score	47.42
				Reported Health Transition	2.00
				Physical Functioning Score	42.46
				Role/Physical Score	49.17
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	51.71
				Bodily Pain Score	42.19

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1749 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	52.72
				Vitality Score	49.05
				Physical Component Summary	45.33
				Mental Component Summary	40.68
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1751 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	45.82
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	49.17
				Role Emotional Score	44.81
				Social Functioning Score	51.71
				Bodily Pain Score	46.48
				Mental Health Score	43.63
				Vitality Score	46.69

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1752 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	48.63
				Mental Component Summary	42.05
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1753 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	No
				How much bodily pain have you had during the past 4 weeks?	Yes
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Yes
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Mild
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1754 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
				Global Health Score	50.61
				Reported Health Transition	2.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	50.44
				Vitality Score	46.69
				Physical Component Summary	46.55
				Mental Component Summary	38.25

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1755 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1756 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1757 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	49.01
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	52.72
				Vitality Score	49.05
				Physical Component Summary	45.68
				Mental Component Summary	41.40
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1758 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1759 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1760 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	39.44
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	54.99
				Vitality Score	53.79
				Physical Component Summary	42.92
				Mental Component Summary	43.76
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1762 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1763 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
			Visit 9	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	49.01
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	48.78
				Mental Component Summary	41.97
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1765 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1766 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	47.42
				Reported Health Transition	4.00
				Physical Functioning Score	50.85
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	43.63
				Vitality Score	49.05
				Physical Component Summary	48.92
				Mental Component Summary	35.16
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1768 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1769 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 11	Global Health Score	45.82
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	49.55
				Mental Component Summary	42.48
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1770 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1771 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1772 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	42.46
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	29.35
				Mental Health Score	34.54
				Vitality Score	34.85
				Physical Component Summary	42.98
				Mental Component Summary	38.12
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1775 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	50.61
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1776 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	48.75
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	29.35
				Mental Health Score	50.44
				Vitality Score	46.69
				Physical Component Summary	41.69
				Mental Component Summary	47.24
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1777 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1778 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	47.42
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1779 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 5	Mental Health Score	48.17
				Vitality Score	56.15
				Physical Component Summary	48.23
				Mental Component Summary	40.03
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1781 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 6	Global Health Score	49.01
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	48.17
				Vitality Score	56.15

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1782 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	47.81
				Mental Component Summary	38.92
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1783 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1784 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	48.75
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	42.19
				Mental Health Score	52.72
				Vitality Score	46.69
				Physical Component Summary	41.24
				Mental Component Summary	42.70

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1785 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 8	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 8	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1787 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 9	Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	58.52
				Physical Component Summary	50.67
				Mental Component Summary	43.11
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1788 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 9	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1789 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 9	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1790 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 10	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	50.61
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	50.44
				Vitality Score	51.42
				Physical Component Summary	45.01
				Mental Component Summary	41.32
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1792 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1793 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 10	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	51.61
				Mental Health Score	50.44
				Vitality Score	56.15
				Physical Component Summary	47.26
				Mental Component Summary	39.00
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1795 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 11	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1796 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	52.20
				Reported Health Transition	2.00
				Physical Functioning Score	19.39
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	25.07
				Mental Health Score	32.27
				Vitality Score	32.49
				Physical Component Summary	37.95
				Mental Component Summary	28.49
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1798 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1799 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A good bit of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	47.42
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1800 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	42.46
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	34.54
				Vitality Score	34.85
				Physical Component Summary	45.96
				Mental Component Summary	34.32
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1801 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1802 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 4	Global Health Score	52.20
				Reported Health Transition	4.00
				Physical Functioning Score	48.75
				Role/Physical Score	42.10
				Role Emotional Score	34.27
				Social Functioning Score	46.28
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1803 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	50.44
				Vitality Score	53.79
				Physical Component Summary	46.73
				Mental Component Summary	42.73
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1804 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1805 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	A little of the time
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	43.59
				Reported Health Transition	3.00
				Physical Functioning Score	31.97
				Role/Physical Score	49.17
				Role Emotional Score	55.34
				Social Functioning Score	24.57
				Bodily Pain Score	25.07
				Mental Health Score	41.36
				Vitality Score	39.59

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1806 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	30.86
				Mental Component Summary	43.49
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1807 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1808 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 6	Global Health Score	45.82
				Reported Health Transition	4.00
				Physical Functioning Score	42.46
				Role/Physical Score	49.17
				Role Emotional Score	34.27
				Social Functioning Score	35.42
				Bodily Pain Score	33.20
				Mental Health Score	48.17
				Vitality Score	49.05
				Physical Component Summary	41.18
				Mental Component Summary	39.56

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1809 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1811 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	45.82
				Reported Health Transition	3.00
				Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	35.42
				Bodily Pain Score	37.48
				Mental Health Score	43.63
				Vitality Score	39.59
				Physical Component Summary	42.84
				Mental Component Summary	38.90
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1812 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1813 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1814 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 8	Global Health Score	41.04
				Reported Health Transition	3.00
				Physical Functioning Score	38.27
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	19.14
				Bodily Pain Score	33.20
				Mental Health Score	34.54
				Vitality Score	34.85
				Physical Component Summary	41.39
				Mental Component Summary	29.96
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1816 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1817 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	All of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 9	Global Health Score	40.40
				Reported Health Transition	3.00
				Physical Functioning Score	38.27
				Role/Physical Score	49.17
				Role Emotional Score	44.81
				Social Functioning Score	24.57
				Bodily Pain Score	29.35
				Mental Health Score	45.90
				Vitality Score	39.59
				Physical Component Summary	35.11
				Mental Component Summary	39.31
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1818 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1819 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1820 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 10	Global Health Score	45.82
				Reported Health Transition	5.00
				Physical Functioning Score	46.66
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	48.17
				Vitality Score	44.32
				Physical Component Summary	44.01
				Mental Component Summary	36.28
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1821 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1822 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1823 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 11	Global Health Score	55.39
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	62.75
				Mental Health Score	43.63
				Vitality Score	53.79
				Physical Component Summary	54.00
				Mental Component Summary	30.59
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1824 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1825 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1826 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0615	NDisc basic	ES/SAF	Baseline (Visit 2a)	Global Health Score	43.59
				Reported Health Transition	2.00
				Physical Functioning Score	31.97
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	24.57
				Bodily Pain Score	33.20
				Mental Health Score	34.54
				Vitality Score	39.59
				Physical Component Summary	37.43
				Mental Component Summary	38.52
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1828 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0615	NDisc basic	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1829 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0615	NDisc basic	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1830 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0616	ES	Baseline	(Visit 2a)	Global Health Score	53.16
				Reported Health Transition	1.00
				Physical Functioning Score	23.58
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	58.52
				Physical Component Summary	38.07
				Mental Component Summary	49.23
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1831 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0616	ES	Baseline	(Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1832 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0616	ES	Baseline (Visit 2a)		For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1833 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0617	NDisc plus	ES/SAF	Baseline (Visit 2a)	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	19.39
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	32.61
				Mental Component Summary	50.68
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1834 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0617	NDisc plus	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1835 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0617	NDisc plus	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 3a	Global Health Score	49.01
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1836 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0617	NDisc plus	ES/SAF	Visit 3a	Physical Functioning Score	42.46
				Role/Physical Score	56.24
				Role Emotional Score	34.27
				Social Functioning Score	51.71
				Bodily Pain Score	29.35
				Mental Health Score	41.36
				Vitality Score	49.05
				Physical Component Summary	44.62
				Mental Component Summary	40.08
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1837 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0617	NDisc plus	ES/SAF	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1838 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0617	NDisc plus	ES/SAF	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1839 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0618	ES	Baseline	(Visit 2a)	Global Health Score	48.37
				Reported Health Transition	1.00
				Physical Functioning Score	38.27
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	42.19
				Mental Health Score	52.72
				Vitality Score	49.05
				Physical Component Summary	41.31
				Mental Component Summary	42.50
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1840 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0618	ES	Baseline (Visit 2a)		Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1841 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0618	ES	Baseline (Visit 2a)		For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1842 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	43.59
				Reported Health Transition	2.00
				Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	29.35
				Mental Health Score	45.90
				Vitality Score	49.05
				Physical Component Summary	41.70
				Mental Component Summary	36.33
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1843 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1844 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 3a	Global Health Score	55.39
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1845 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	52.95
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	46.69
				Physical Component Summary	53.22
				Mental Component Summary	38.78
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1846 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1847 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	46.78
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	35.03
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	37.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1848 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	45.90
				Vitality Score	51.42
				Physical Component Summary	43.80
				Mental Component Summary	39.66
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1850 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	48.17
				Vitality Score	56.15

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1851 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	49.44
				Mental Component Summary	40.37
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1852 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1853 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	47.42
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	50.76
				Mental Health Score	50.44
				Vitality Score	58.52
				Physical Component Summary	45.78
				Mental Component Summary	42.63

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1854 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1855 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1856 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	47.33
				Mental Health Score	39.08
				Vitality Score	53.79
				Physical Component Summary	49.45
				Mental Component Summary	35.89
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1857 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1858 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1859 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	38.81
				Reported Health Transition	1.00
				Physical Functioning Score	44.56
				Role/Physical Score	49.17
				Role Emotional Score	55.34
				Social Functioning Score	19.14
				Bodily Pain Score	50.76
				Mental Health Score	14.09
				Vitality Score	25.39
				Physical Component Summary	48.81
				Mental Component Summary	20.13
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1861 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1862 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 9	Global Health Score	37.85
				Reported Health Transition	4.00
				Physical Functioning Score	36.17
				Role/Physical Score	49.17
				Role Emotional Score	55.34
				Social Functioning Score	46.28
				Bodily Pain Score	37.48
				Mental Health Score	20.91
				Vitality Score	32.49
				Physical Component Summary	39.30
				Mental Component Summary	35.64
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1864 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1865 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
			Visit 9	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 10	Global Health Score	32.43
				Reported Health Transition	1.00
				Physical Functioning Score	34.07
				Role/Physical Score	49.17
				Role Emotional Score	44.81
				Social Functioning Score	19.14
				Bodily Pain Score	29.35
				Mental Health Score	16.37
				Vitality Score	27.75
				Physical Component Summary	37.56
				Mental Component Summary	21.81
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1866 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1867 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1868 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 11	Global Health Score	38.81
				Reported Health Transition	2.00
				Physical Functioning Score	29.88
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	35.42
				Bodily Pain Score	37.91
				Mental Health Score	18.64
				Vitality Score	32.49
				Physical Component Summary	42.09
				Mental Component Summary	27.56
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1869 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1870 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1871 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	47.42
				Reported Health Transition	1.00
				Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	34.27
				Social Functioning Score	40.85
				Bodily Pain Score	28.92
				Mental Health Score	36.81
				Vitality Score	39.59
				Physical Component Summary	42.23
				Mental Component Summary	34.24
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1873 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1874 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 4	Global Health Score	49.01
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1875 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	50.85
				Role/Physical Score	49.17
				Role Emotional Score	34.27
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	54.99
				Vitality Score	49.05
				Physical Component Summary	48.08
				Mental Component Summary	45.44
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1877 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	49.01
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	56.24
				Role Emotional Score	44.81
			Visit 5	Social Functioning Score	57.14
				Bodily Pain Score	42.19

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1878 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 5	Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	47.25
				Mental Component Summary	50.11
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1880 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 6	Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	37.48
				Mental Health Score	48.17
				Vitality Score	51.42

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1881 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	50.15
				Mental Component Summary	37.02
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1882 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1883 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	49.01
				Reported Health Transition	5.00
				Physical Functioning Score	48.75
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	47.30
				Mental Component Summary	41.67

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1884 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1886 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
				Global Health Score	47.42
				Reported Health Transition	3.00
				Physical Functioning Score	48.75
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	46.48
				Mental Health Score	52.72
				Vitality Score	53.79
				Physical Component Summary	44.53
				Mental Component Summary	41.67
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1887 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1888 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1889 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
			Visit 9	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	41.77
				Mental Health Score	48.17
				Vitality Score	49.05
				Physical Component Summary	47.67
				Mental Component Summary	37.43
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1891 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1892 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
			Visit 10	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
				Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	52.72
				Vitality Score	49.05
				Physical Component Summary	45.64
				Mental Component Summary	41.51
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1894 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1895 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 11	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	41.77
				Mental Health Score	57.26
				Vitality Score	53.79
				Physical Component Summary	46.56
				Mental Component Summary	44.36
		In general, would you say your health is:	Good		
		Compared to one year ago, how would you rate your health in general now?	About the same as one year ago		
		Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little		
		Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little		
		Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1896 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1897 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1898 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	47.42
				Reported Health Transition	1.00
				Physical Functioning Score	38.27
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	30.00
				Bodily Pain Score	25.07
				Mental Health Score	43.63
				Vitality Score	49.05
				Physical Component Summary	42.77
				Mental Component Summary	32.18
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1900 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1901 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	All of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	49.01
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1902 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	51.61
				Mental Health Score	48.17
				Vitality Score	51.42
				Physical Component Summary	53.25
				Mental Component Summary	33.81
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1903 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1904 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	46.28
				Bodily Pain Score	54.18

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1905 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	46.15
				Mental Component Summary	39.24
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1907 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	45.90
				Vitality Score	49.05

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1908 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	50.10
				Mental Component Summary	35.73
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1909 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1910 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
				Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	50.44
				Vitality Score	51.42
				Physical Component Summary	47.93
				Mental Component Summary	40.32

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1911 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1912 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1913 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	50.44
				Vitality Score	53.79
				Physical Component Summary	48.00
				Mental Component Summary	40.87
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1914 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1915 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1916 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	47.89
				Mental Component Summary	42.13
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1918 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1919 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	50.44
				Vitality Score	49.05
				Physical Component Summary	48.83
				Mental Component Summary	39.37
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1921 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1922 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	50.08
				Mental Component Summary	40.82
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1923 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1924 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1925 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	41.77
				Mental Health Score	50.44
				Vitality Score	53.79
				Physical Component Summary	43.22
				Mental Component Summary	38.42
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1926 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1927 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1928 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	32.43
				Reported Health Transition	1.00
				Physical Functioning Score	15.19
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	19.93
				Mental Health Score	20.91
				Vitality Score	23.02
				Physical Component Summary	25.77
				Mental Component Summary	36.24
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1930 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1931 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 4	Global Health Score	36.26
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1932 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	31.97
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	33.20
				Mental Health Score	32.27
				Vitality Score	37.22
				Physical Component Summary	35.95
				Mental Component Summary	39.89
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1933 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1934 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 5	Global Health Score	41.04
				Reported Health Transition	4.00
				Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	55.34
			Visit 5	Social Functioning Score	30.00
				Bodily Pain Score	37.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1935 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Visit 5	Mental Health Score	25.45
				Vitality Score	37.22
				Physical Component Summary	41.83
				Mental Component Summary	33.66
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1936 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1937 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 6	Global Health Score	44.23
				Reported Health Transition	4.00
				Physical Functioning Score	48.75
				Role/Physical Score	42.10
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	46.48
				Mental Health Score	11.82
				Vitality Score	27.75

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1938 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	48.55
				Mental Component Summary	24.20
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1939 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	All of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1940 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
				Global Health Score	42.63
				Reported Health Transition	2.00
				Physical Functioning Score	46.66
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	30.00
				Bodily Pain Score	37.91
				Mental Health Score	20.91
				Vitality Score	30.12
				Physical Component Summary	47.61
				Mental Component Summary	27.31

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1941 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Visit 8	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Visit 8	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1943 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 10	Global Health Score	40.40
				Reported Health Transition	2.00
				Physical Functioning Score	42.46
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	30.00
				Bodily Pain Score	29.35
				Mental Health Score	23.18
				Vitality Score	30.12
				Physical Component Summary	42.05
				Mental Component Summary	30.24
				In general, would you say your health is:	Fair

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1944 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Visit 10	Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1945 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Visit 10	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1946 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Visit 10	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	25.68
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	19.93
				Mental Health Score	43.63
				Vitality Score	51.42
				Physical Component Summary	31.14
				Mental Component Summary	43.69
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1948 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1949 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	47.42
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1950 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	50.85
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	51.61
				Mental Health Score	50.44
				Vitality Score	58.52
				Physical Component Summary	50.21
				Mental Component Summary	38.37
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1951 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1952 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	50.61
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.05

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1953 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	48.17
				Vitality Score	56.15
				Physical Component Summary	46.40
				Mental Component Summary	40.89
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1954 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1955 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	53.79

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1956 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	51.63
				Mental Component Summary	39.36
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1957 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1958 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	48.17
				Vitality Score	56.15
				Physical Component Summary	52.99
				Mental Component Summary	38.76

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1959 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1960 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1961 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	48.46
				Mental Component Summary	42.05
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1962 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1963 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1964 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	52.72
				Vitality Score	58.52
				Physical Component Summary	50.28
				Mental Component Summary	42.17
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1965 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1966 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1967 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	58.52
				Physical Component Summary	49.78
				Mental Component Summary	43.27
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1969 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1970 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	55.39
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	52.79
				Mental Component Summary	40.92
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1971 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1972 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1973 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	54.18
				Mental Health Score	48.17
				Vitality Score	53.79
				Physical Component Summary	50.21
				Mental Component Summary	39.04
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1974 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1975 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1976 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	56.98
				Reported Health Transition	4.00
				Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	33.20
				Mental Health Score	54.99
				Vitality Score	41.95
				Physical Component Summary	44.02
				Mental Component Summary	39.95
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1979 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 3a	Global Health Score	59.53
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1980 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	50.44
				Vitality Score	56.15
				Physical Component Summary	51.26
				Mental Component Summary	40.90
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1982 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 4	Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1983 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	47.03
				Mental Component Summary	44.04
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1985 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 5	Global Health Score	56.98
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	50.76
				Mental Health Score	52.72
				Vitality Score	58.52

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1986 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	48.56
				Mental Component Summary	43.10
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1987 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1988 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	47.13
				Mental Component Summary	42.96

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1989 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1991 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 7	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	50.61
				Mental Component Summary	41.59
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1992 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1993 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1994 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 8	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	53.79
				Physical Component Summary	52.22
				Mental Component Summary	41.47
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1995 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1996 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1997 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	58.58
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	60.89
				Physical Component Summary	52.72
				Mental Component Summary	44.19
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 1999 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2000 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 10	Global Health Score	52.20
				Reported Health Transition	2.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	54.99
				Vitality Score	58.52
				Physical Component Summary	47.13
				Mental Component Summary	44.20
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2001 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2002 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2003 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	58.52
				Physical Component Summary	51.97
				Mental Component Summary	41.96
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2004 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2005 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2006 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0705	ES	Baseline	(Visit 2a)	Global Health Score	38.81
				Reported Health Transition	1.00
				Physical Functioning Score	19.39
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	19.93
				Mental Health Score	30.00
				Vitality Score	32.49
				Physical Component Summary	33.35
				Mental Component Summary	32.48
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2008 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0705	ES	Baseline	(Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2009 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0705	ES	Baseline (Visit 2a)		For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2010 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0706	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	30.83
				Reported Health Transition	1.00
				Physical Functioning Score	17.29
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	30.00
				Bodily Pain Score	19.93
				Mental Health Score	39.08
				Vitality Score	23.02
				Physical Component Summary	28.36
				Mental Component Summary	29.44
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2011 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0706	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2012 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0706	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 4	Global Health Score	30.83
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2013 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0706	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	31.97
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	34.54
				Vitality Score	23.02
				Physical Component Summary	35.01
				Mental Component Summary	38.78
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0706	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2015 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0706	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2016 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0707	ES	Baseline	(Visit 2a)	Global Health Score	53.79
				Reported Health Transition	1.00
				Physical Functioning Score	23.58
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	29.35
				Mental Health Score	41.36
				Vitality Score	37.22
				Physical Component Summary	39.61
				Mental Component Summary	32.61
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2017 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0707	ES	Baseline (Visit 2a)		Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2018 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0707	ES	Baseline (Visit 2a)		For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2019 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0801	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	46.78
				Reported Health Transition	1.00
				Physical Functioning Score	21.49
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	19.93
				Mental Health Score	30.00
				Vitality Score	32.49
				Physical Component Summary	36.31
				Mental Component Summary	28.95
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2020 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0801	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2021 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0801	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 4	Global Health Score	55.39
				Reported Health Transition	4.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2022 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0801	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	31.97
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	32.27
				Vitality Score	41.95
				Physical Component Summary	48.25
				Mental Component Summary	28.03
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2023 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0801	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2024 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0801	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	55.39
				Reported Health Transition	4.00
				Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	23.74
			Visit 5	Social Functioning Score	51.71
				Bodily Pain Score	41.77

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2025 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0801	SC	ES/SAF/FAS	Visit 5	Mental Health Score	50.44
				Vitality Score	44.32
				Physical Component Summary	49.15
				Mental Component Summary	37.98
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0801	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2027 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0801	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 6	Global Health Score	55.39
				Reported Health Transition	4.00
				Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	33.63
				Mental Health Score	41.36
				Vitality Score	39.59

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2028 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0801	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	46.69
				Mental Component Summary	32.75
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2029 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0801	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2030 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0801	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	50.61
				Reported Health Transition	2.00
				Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	24.57
				Bodily Pain Score	37.48
				Mental Health Score	32.27
				Vitality Score	32.49
				Physical Component Summary	50.47
				Mental Component Summary	19.57
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2032 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2033 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	53.79
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2034 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	50.85
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	48.17
				Vitality Score	46.69
				Physical Component Summary	50.33
				Mental Component Summary	34.88
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2035 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2036 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	35.03
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	46.28
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2037 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	49.54
				Mental Component Summary	40.28
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2039 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	53.79
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	55.90
				Mental Health Score	52.72
				Vitality Score	49.05

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2040 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	48.31
				Mental Component Summary	37.99
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2041 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2042 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	50.61
				Reported Health Transition	4.00
				Physical Functioning Score	50.85
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	52.72
				Vitality Score	44.32
				Physical Component Summary	48.47
				Mental Component Summary	36.58

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2043 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2044 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2045 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	53.79
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	51.61
				Mental Health Score	52.72
				Vitality Score	49.05
				Physical Component Summary	46.95
				Mental Component Summary	38.40
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2046 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2047 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2048 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
			Visit 8	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	34.27
				Social Functioning Score	40.85
				Bodily Pain Score	46.48
				Mental Health Score	43.63
				Vitality Score	46.69
				Physical Component Summary	45.28
				Mental Component Summary	37.05
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2050 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2051 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	48.75
				Role/Physical Score	27.95
				Role Emotional Score	34.27
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	36.81
				Vitality Score	39.59
				Physical Component Summary	44.36
				Mental Component Summary	34.51
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2052 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2053 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2054 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 10	Global Health Score	45.82
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	35.03
				Role Emotional Score	34.27
				Social Functioning Score	40.85
				Bodily Pain Score	42.19
				Mental Health Score	43.63
				Vitality Score	39.59
				Physical Component Summary	44.21
				Mental Component Summary	35.04
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2055 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2056 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2057 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 11	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	46.48
				Mental Health Score	48.17
				Vitality Score	46.69
				Physical Component Summary	47.50
				Mental Component Summary	37.09
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2058 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2059 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2060 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0803	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	49.01
				Reported Health Transition	2.00
				Physical Functioning Score	44.56
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	51.61
				Mental Health Score	41.36
				Vitality Score	41.95
				Physical Component Summary	52.00
				Mental Component Summary	29.14
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2062 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0803	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2063 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0803	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 3a	Global Health Score	52.20
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2064 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0803	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	43.63
				Vitality Score	44.32
				Physical Component Summary	48.38
				Mental Component Summary	34.36
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0803	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2066 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0803	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	56.24
				Role Emotional Score	55.34
			Visit 4	Social Functioning Score	30.00
				Bodily Pain Score	19.93

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2067 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0803	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	30.00
				Vitality Score	39.59
				Physical Component Summary	45.71
				Mental Component Summary	33.64
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2068 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0803	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2069 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0803	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	55.90
				Mental Health Score	43.63
				Vitality Score	49.05

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2070 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0803	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	52.45
				Mental Component Summary	34.04
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2071 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0803	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2072 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0803	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	52.20
				Reported Health Transition	2.00
				Physical Functioning Score	29.88
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	19.93
				Mental Health Score	52.72
				Vitality Score	49.05
				Physical Component Summary	36.60
				Mental Component Summary	44.79
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2074 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2075 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	58.58
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2076 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	50.28
				Mental Component Summary	42.31
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2078 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 4	Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2079 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	54.99
				Vitality Score	53.79
				Physical Component Summary	47.30
				Mental Component Summary	43.49
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2081 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	56.15

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2082 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	52.68
				Mental Component Summary	42.00
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2083 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2084 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	50.44
				Vitality Score	56.15
				Physical Component Summary	49.66
				Mental Component Summary	41.33

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2085 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2086 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2087 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 7	Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	56.15
				Physical Component Summary	52.58
				Mental Component Summary	43.08
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2088 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2089 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2090 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 8	Global Health Score	56.98
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	37.48
				Mental Health Score	57.26
				Vitality Score	53.79
				Physical Component Summary	43.20
				Mental Component Summary	45.49
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2092 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2093 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	56.15
				Physical Component Summary	52.58
				Mental Component Summary	43.08
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2095 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2096 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 10	Global Health Score	56.98
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	50.76
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	46.21
				Mental Component Summary	44.61
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2097 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2098 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2099 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	56.15
				Physical Component Summary	51.69
				Mental Component Summary	43.56
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2100 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2101 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2102 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	35.62
				Reported Health Transition	1.00
				Physical Functioning Score	31.97
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	33.20
				Mental Health Score	20.91
				Vitality Score	25.39
				Physical Component Summary	37.96
				Mental Component Summary	31.60
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2104 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2105 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 3a	Global Health Score	44.39
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2106 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	50.85
				Role/Physical Score	35.03
				Role Emotional Score	44.81
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	41.36
				Vitality Score	44.32
				Physical Component Summary	42.89
				Mental Component Summary	41.17
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2107 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2108 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	38.81
				Reported Health Transition	2.00
				Physical Functioning Score	48.75
				Role/Physical Score	49.17
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	37.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2109 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	32.27
				Vitality Score	30.12
				Physical Component Summary	42.38
				Mental Component Summary	34.77
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2110 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2111 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	49.01
				Reported Health Transition	2.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	34.27
				Social Functioning Score	46.28
				Bodily Pain Score	50.76
				Mental Health Score	39.08
				Vitality Score	41.95

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2112 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	47.16
				Mental Component Summary	34.36
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2113 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2114 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
			Visit 6	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	55.90
				Mental Health Score	48.17
				Vitality Score	56.15
				Physical Component Summary	51.26
				Mental Component Summary	37.94

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2115 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2116 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2117 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	49.01
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	55.90
				Mental Health Score	43.63
				Vitality Score	51.42
				Physical Component Summary	50.08
				Mental Component Summary	33.72
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2118 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2119 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2120 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	49.01
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	44.81
				Social Functioning Score	46.28
				Bodily Pain Score	46.05
				Mental Health Score	20.91
				Vitality Score	44.32
				Physical Component Summary	48.61
				Mental Component Summary	30.64
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2122 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2123 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	35.62
				Reported Health Transition	2.00
				Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	30.00
				Bodily Pain Score	41.77
				Mental Health Score	14.09
				Vitality Score	30.12
				Physical Component Summary	45.92
				Mental Component Summary	25.18
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2125 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2126 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 10	Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	50.76
				Mental Health Score	43.63
				Vitality Score	49.05
				Physical Component Summary	48.34
				Mental Component Summary	35.12
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2128 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2129 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	46.05
				Mental Health Score	41.36
				Vitality Score	51.42
				Physical Component Summary	49.50
				Mental Component Summary	34.48
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2130 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2131 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2132 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	49.01
				Reported Health Transition	2.00
				Physical Functioning Score	21.49
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	51.61
				Mental Health Score	20.91
				Vitality Score	34.85
				Physical Component Summary	49.05
				Mental Component Summary	20.52
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2134 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2135 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	All of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	52.20
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2136 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	46.66
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	42.19
				Mental Health Score	39.08
				Vitality Score	46.69
				Physical Component Summary	51.29
				Mental Component Summary	31.00
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2137 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2138 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	35.03
				Role Emotional Score	34.27
				Social Functioning Score	57.14
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2139 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	30.00
				Vitality Score	41.95
				Physical Component Summary	50.85
				Mental Component Summary	32.82
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2141 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	46.66
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	36.81
				Vitality Score	44.32

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2142 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	48.11
				Mental Component Summary	30.66
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2143 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2144 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 6	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	48.75
				Role/Physical Score	42.10
				Role Emotional Score	34.27
				Social Functioning Score	35.42
				Bodily Pain Score	55.90
				Mental Health Score	27.73
				Vitality Score	41.95
				Physical Component Summary	54.07
				Mental Component Summary	25.10

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2145 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2146 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2147 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	48.75
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	54.18
				Mental Health Score	25.45
				Vitality Score	39.59
				Physical Component Summary	54.89
				Mental Component Summary	31.01
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2148 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2149 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2150 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
			Visit 8	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	48.75
				Role/Physical Score	27.95
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	55.90
				Mental Health Score	7.28
				Vitality Score	25.39
				Physical Component Summary	48.70
				Mental Component Summary	22.18
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2152 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	All of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2153 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	All of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	49.01
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	42.10
				Role Emotional Score	44.81
				Social Functioning Score	40.85
				Bodily Pain Score	50.76
				Mental Health Score	18.64
				Vitality Score	32.49
				Physical Component Summary	52.60
				Mental Component Summary	24.53
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2155 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	All of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2156 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 10	Global Health Score	49.01
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	34.27
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	27.73
				Vitality Score	39.59
				Physical Component Summary	48.24
				Mental Component Summary	28.70
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2157 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2158 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2159 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 11	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	44.81
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	23.18
				Vitality Score	39.59
				Physical Component Summary	48.41
				Mental Component Summary	30.99
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2160 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2161 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2162 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	45.18
				Reported Health Transition	1.00
				Physical Functioning Score	25.68
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	24.57
				Bodily Pain Score	19.93
				Mental Health Score	14.09
				Vitality Score	25.39
				Physical Component Summary	35.05
				Mental Component Summary	27.96
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2164 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2165 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	45.18
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2166 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	29.18
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	24.57
				Bodily Pain Score	28.92
				Mental Health Score	34.54
				Vitality Score	23.02
				Physical Component Summary	34.81
				Mental Component Summary	35.65
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2167 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2168 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 4	Global Health Score	45.18
				Reported Health Transition	2.00
				Physical Functioning Score	42.46
				Role/Physical Score	56.24
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	40.85
				Bodily Pain Score	29.35

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2169 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	41.36
				Vitality Score	30.12
				Physical Component Summary	45.22
				Mental Component Summary	28.20
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2170 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2171 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	45.90
				Vitality Score	46.69

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2172 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	46.62
				Mental Component Summary	37.99
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2173 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2174 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	49.01
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	41.36
				Vitality Score	25.39
				Physical Component Summary	44.98
				Mental Component Summary	31.29

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2175 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2176 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2177 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	45.82
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	41.36
				Vitality Score	34.85
				Physical Component Summary	48.57
				Mental Component Summary	32.20
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2178 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2179 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2180 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 8	Global Health Score	49.01
				Reported Health Transition	2.00
				Physical Functioning Score	48.75
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	37.48
				Mental Health Score	43.63
				Vitality Score	37.22
				Physical Component Summary	51.01
				Mental Component Summary	33.05
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2182 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2183 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	47.42
				Reported Health Transition	3.00
				Physical Functioning Score	27.78
				Role/Physical Score	56.24
				Role Emotional Score	34.27
				Social Functioning Score	57.14
				Bodily Pain Score	33.20
				Mental Health Score	57.26
				Vitality Score	49.05
				Physical Component Summary	35.67
				Mental Component Summary	52.29
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2185 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2186 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 4	Global Health Score	49.01
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2187 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	38.27
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	37.91
				Mental Health Score	54.99
				Vitality Score	46.69
				Physical Component Summary	44.63
				Mental Component Summary	37.33
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2188 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2189 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	47.42
				Reported Health Transition	2.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	47.33

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2190 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 5	Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	42.82
				Mental Component Summary	42.18
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2192 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 6	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	53.79

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2193 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	49.15
				Mental Component Summary	42.61
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2194 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2195 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	47.89
				Mental Component Summary	42.13

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2196 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2197 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2198 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	45.82
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	53.79
				Physical Component Summary	48.94
				Mental Component Summary	42.10
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2199 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2200 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2201 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 9	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	53.79
				Physical Component Summary	51.93
				Mental Component Summary	39.77
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2203 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2204 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	53.79
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	58.52
				Physical Component Summary	49.78
				Mental Component Summary	43.27
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2206 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2207 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	57.26
				Vitality Score	53.79
				Physical Component Summary	48.75
				Mental Component Summary	43.29
		In general, would you say your health is:	Very good		
		Compared to one year ago, how would you rate your health in general now?	About the same as one year ago		
		Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all		
		Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all		
		Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2208 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2209 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2210 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	52.20
				Reported Health Transition	1.00
				Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	29.35
				Mental Health Score	48.17
				Vitality Score	51.42
				Physical Component Summary	45.15
				Mental Component Summary	38.35
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2212 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2213 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	49.01
				Reported Health Transition	1.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2214 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	28.92
				Mental Health Score	50.44
				Vitality Score	58.52
				Physical Component Summary	44.01
				Mental Component Summary	38.30
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2215 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2216 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 5	Global Health Score	55.39
				Reported Health Transition	2.00
				Physical Functioning Score	46.66
				Role/Physical Score	35.03
				Role Emotional Score	23.74
			Visit 5	Social Functioning Score	46.28
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2217 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 5	Mental Health Score	50.44
				Vitality Score	58.52
				Physical Component Summary	46.31
				Mental Component Summary	40.58
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2219 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 6	Global Health Score	55.39
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	50.76
				Mental Health Score	54.99
				Vitality Score	60.89

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2220 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	46.84
				Mental Component Summary	45.27
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2221 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2222 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	56.98
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	50.76
				Mental Health Score	52.72
				Vitality Score	60.89
				Physical Component Summary	52.04
				Mental Component Summary	40.84

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2223 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2225 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	52.20
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	49.82
				Mental Component Summary	41.64
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2226 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2227 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2228 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	56.98
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	60.89
				Physical Component Summary	50.64
				Mental Component Summary	43.78
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2230 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2231 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 10	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	56.98
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	58.52
				Physical Component Summary	52.75
				Mental Component Summary	42.55
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2233 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2234 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 11	Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	58.52
				Physical Component Summary	53.15
				Mental Component Summary	42.53
		In general, would you say your health is:	Very good		
		Compared to one year ago, how would you rate your health in general now?	About the same as one year ago		
		Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all		
		Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all		
		Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2235 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2236 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2237 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0903	NDisc plus	ES/SAF	Baseline (Visit 2a)	Global Health Score	40.40
				Reported Health Transition	1.00
				Physical Functioning Score	25.68
				Role/Physical Score	42.10
				Role Emotional Score	44.81
				Social Functioning Score	13.71
				Bodily Pain Score	29.35
				Mental Health Score	25.45
				Vitality Score	25.39
				Physical Component Summary	31.48
				Mental Component Summary	26.89
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2239 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0903	NDisc plus	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2240 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0903	NDisc plus	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	All of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 3a	Global Health Score	40.40
				Reported Health Transition	4.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2241 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0903	NDisc plus	ES/SAF	Visit 3a	Physical Functioning Score	31.97
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	13.71
				Bodily Pain Score	19.93
				Mental Health Score	34.54
				Vitality Score	39.59
				Physical Component Summary	33.61
				Mental Component Summary	24.97
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2242 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0903	NDisc plus	ES/SAF	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2243 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0903	NDisc plus	ES/SAF	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	All of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2244 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	21.49
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	24.57
				Bodily Pain Score	29.35
				Mental Health Score	23.18
				Vitality Score	34.85
				Physical Component Summary	38.70
				Mental Component Summary	29.94
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2245 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2246 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 3a	Global Health Score	49.01
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2247 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	47.82
				Role/Physical Score	49.17
				Role Emotional Score	44.81
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	36.81
				Vitality Score	51.42
				Physical Component Summary	46.12
				Mental Component Summary	38.93
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2248 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2249 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 4	Global Health Score	45.82
				Reported Health Transition	5.00
				Physical Functioning Score	46.66
				Role/Physical Score	56.24
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	40.85
				Bodily Pain Score	41.77

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2250 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	39.08
				Vitality Score	51.42
				Physical Component Summary	52.22
				Mental Component Summary	29.92
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2251 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2252 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	47.42
				Reported Health Transition	4.00
				Physical Functioning Score	44.56
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	42.19
				Mental Health Score	34.54
				Vitality Score	49.05

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2253 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	50.32
				Mental Component Summary	28.45
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2254 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2255 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	50.61
				Reported Health Transition	4.00
				Physical Functioning Score	47.82
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	46.48
				Mental Health Score	39.08
				Vitality Score	56.15
				Physical Component Summary	50.57
				Mental Component Summary	31.98

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2256 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2257 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2258 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
				Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	47.33
				Mental Health Score	45.90
				Vitality Score	56.15
				Physical Component Summary	51.47
				Mental Component Summary	35.49
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2259 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2260 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2261 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 8	Global Health Score	42.63
				Reported Health Transition	2.00
				Physical Functioning Score	48.75
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	41.36
				Vitality Score	46.69
				Physical Component Summary	49.08
				Mental Component Summary	39.63
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2263 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2264 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 9	Global Health Score	40.40
				Reported Health Transition	2.00
				Physical Functioning Score	40.36
				Role/Physical Score	49.17
				Role Emotional Score	34.27
				Social Functioning Score	40.85
				Bodily Pain Score	46.48
				Mental Health Score	30.00
				Vitality Score	44.32
				Physical Component Summary	46.99
				Mental Component Summary	30.36
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2265 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2266 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2267 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 10	Global Health Score	45.82
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	46.48
				Mental Health Score	36.81
				Vitality Score	39.59
				Physical Component Summary	51.50
				Mental Component Summary	28.79
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2268 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2269 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2270 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 11	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	46.48
				Mental Health Score	39.08
				Vitality Score	58.52
				Physical Component Summary	47.27
				Mental Component Summary	36.48
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2271 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2272 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2273 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	48.37
				Reported Health Transition	1.00
				Physical Functioning Score	24.52
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	55.90
				Mental Health Score	41.36
				Vitality Score	56.15
				Physical Component Summary	47.51
				Mental Component Summary	38.73
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2275 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2276 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	50.61
				Reported Health Transition	4.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2277 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	36.17
				Role/Physical Score	49.17
				Role Emotional Score	44.81
				Social Functioning Score	57.14
				Bodily Pain Score	37.48
				Mental Health Score	45.90
				Vitality Score	46.69
				Physical Component Summary	39.31
				Mental Component Summary	49.27
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2278 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2279 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	44.23
				Reported Health Transition	4.00
				Physical Functioning Score	34.07
				Role/Physical Score	56.24
				Role Emotional Score	55.34
			Visit 4	Social Functioning Score	40.85
				Bodily Pain Score	37.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2280 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	36.81
				Vitality Score	32.49
				Physical Component Summary	39.01
				Mental Component Summary	41.42
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2281 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2282 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	52.20
				Reported Health Transition	4.00
				Physical Functioning Score	42.46
				Role/Physical Score	
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	37.48
				Mental Health Score	45.90
				Vitality Score	46.69

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2283 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary Mental Component Summary	
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2284 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2285 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	55.90
				Mental Health Score	48.17
				Vitality Score	51.42
				Physical Component Summary	50.58
				Mental Component Summary	36.26

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2286 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2288 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	42.63
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	51.61
				Mental Health Score	48.17
				Vitality Score	51.42
				Physical Component Summary	46.98
				Mental Component Summary	37.42
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2289 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2290 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2291 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	47.42
				Reported Health Transition	3.00
				Physical Functioning Score	52.48
				Role/Physical Score	27.95
				Role Emotional Score	55.34
				Social Functioning Score	46.28
				Bodily Pain Score	50.76
				Mental Health Score	45.90
				Vitality Score	53.79
				Physical Component Summary	40.46
				Mental Component Summary	50.22
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2292 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2293 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2294 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
			Visit 9	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	51.61
				Mental Health Score	48.17
				Vitality Score	53.79
				Physical Component Summary	49.33
				Mental Component Summary	35.49
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2296 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2297 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	50.61
				Reported Health Transition	4.00
				Physical Functioning Score	38.27
				Role/Physical Score	42.10
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	37.48
				Mental Health Score	48.17
				Vitality Score	49.05
				Physical Component Summary	35.43
				Mental Component Summary	50.05
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2299 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2300 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	49.01
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	51.61
				Mental Health Score	48.17
				Vitality Score	51.42
				Physical Component Summary	47.76
				Mental Component Summary	34.89
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2301 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2302 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2303 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0906	ES		Baseline (Visit 2a)	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	31.97
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	33.63
				Mental Health Score	48.17
				Vitality Score	34.85
				Physical Component Summary	39.52
				Mental Component Summary	39.78
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2305 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0906	ES	Baseline	(Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2306 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0906	ES	Baseline (Visit 2a)		For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2307 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	55.39
				Reported Health Transition	2.00
				Physical Functioning Score	38.27
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	48.17
				Vitality Score	37.22
				Physical Component Summary	50.01
				Mental Component Summary	36.69
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2308 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2309 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	55.39
				Reported Health Transition	4.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2310 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	49.05
				Physical Component Summary	57.68
				Mental Component Summary	37.55
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2311 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2312 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 5	Social Functioning Score	57.14
				Bodily Pain Score	55.90

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2313 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 5	Mental Health Score	52.72
				Vitality Score	53.79
				Physical Component Summary	48.76
				Mental Component Summary	41.99
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2315 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 6	Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	54.99
				Vitality Score	51.42

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2316 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	48.12
				Mental Component Summary	42.45
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2317 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2318 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	53.79
				Physical Component Summary	50.44
				Mental Component Summary	42.11

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2319 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2320 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2321 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	43.59
				Reported Health Transition	2.00
				Physical Functioning Score	55.05
				Role/Physical Score	49.17
				Role Emotional Score	34.27
				Social Functioning Score	57.14
				Bodily Pain Score	49.90
				Mental Health Score	43.63
				Vitality Score	34.85
				Physical Component Summary	51.69
				Mental Component Summary	35.37
				In general, would you say your health is:	Fair

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2322 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2323 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2324 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 9	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	46.69
				Physical Component Summary	53.02
				Mental Component Summary	37.59
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2325 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2326 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2327 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
			Visit 10	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	53.79
				Physical Component Summary	52.22
				Mental Component Summary	41.47
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2329 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2330 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	56.98
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	52.68
				Mental Component Summary	42.00
		In general, would you say your health is:	Very good		
		Compared to one year ago, how would you rate your health in general now?	About the same as one year ago		
		Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all		
		Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all		
		Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2331 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2332 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2333 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	36.17
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	19.93
				Mental Health Score	50.44
				Vitality Score	58.52
				Physical Component Summary	41.60
				Mental Component Summary	45.83
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2335 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2336 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 3a	Global Health Score	59.53
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2337 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	60.89
				Physical Component Summary	53.46
				Mental Component Summary	43.07
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2338 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2339 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 4	Global Health Score	53.16
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2340 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	50.44
				Vitality Score	58.52
				Physical Component Summary	52.80
				Mental Component Summary	40.41
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2341 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2342 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 5	Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	58.52

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2343 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	53.15
				Mental Component Summary	42.53
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2344 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2345 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	59.53
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	53.32
				Mental Component Summary	41.96

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2346 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2347 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2348 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 7	Global Health Score	59.53
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	58.52
				Physical Component Summary	53.39
				Mental Component Summary	42.51
				In general, would you say your health is:	Excellent

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2349 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2350 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2351 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 8	Global Health Score	59.53
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	52.72
				Vitality Score	58.52
				Physical Component Summary	51.71
				Mental Component Summary	42.08
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2352 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2353 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2354 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 9	Global Health Score	53.16
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	51.73
				Mental Component Summary	42.06
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2356 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2357 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 10	Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	58.52
				Physical Component Summary	52.65
				Mental Component Summary	43.63
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2358 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2359 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2360 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 11	Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	60.89
				Physical Component Summary	53.22
				Mental Component Summary	43.09
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2361 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2362 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2363 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	45.82
				Reported Health Transition	1.00
				Physical Functioning Score	15.19
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	30.00
				Bodily Pain Score	29.35
				Mental Health Score	36.81
				Vitality Score	41.95
				Physical Component Summary	35.25
				Mental Component Summary	32.12
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2365 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2366 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 3a	Global Health Score	56.98
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2367 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	48.75
				Role/Physical Score	49.17
				Role Emotional Score	44.81
				Social Functioning Score	46.28
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	46.69
				Physical Component Summary	52.84
				Mental Component Summary	44.21
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2368 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2369 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	48.75
				Role/Physical Score	42.10
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2370 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	50.02
				Mental Component Summary	42.18
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2371 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2372 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	48.17
				Vitality Score	56.15

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2373 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	51.12
				Mental Component Summary	40.16
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2374 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2375 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	35.03
				Role Emotional Score	34.27
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	48.17
				Vitality Score	56.15
				Physical Component Summary	54.16
				Mental Component Summary	42.84

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2376 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2377 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2378 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	51.61
				Mental Health Score	50.44
				Vitality Score	53.79
				Physical Component Summary	47.99
				Mental Component Summary	38.39
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2379 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2380 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2381 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	58.52
				Physical Component Summary	51.56
				Mental Component Summary	42.63
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2382 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2383 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2384 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 9	Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	60.89
				Physical Component Summary	52.82
				Mental Component Summary	43.11
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2385 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2386 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2387 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	56.98
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	55.67
				Mental Component Summary	40.02
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2388 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2389 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2390 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 11	Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	53.58
				Mental Component Summary	40.87
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2391 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2392 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2393 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0910	NDisc plus	ES/SAF	Baseline (Visit 2a)	Global Health Score	45.18
				Reported Health Transition	1.00
				Physical Functioning Score	15.19
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	19.14
				Bodily Pain Score	19.93
				Mental Health Score	20.91
				Vitality Score	23.02
				Physical Component Summary	29.07
				Mental Component Summary	31.66
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2395 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0910	NDisc plus	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2396 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0910	NDisc plus	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2397 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	50.61
				Reported Health Transition	1.00
				Physical Functioning Score	25.68
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	24.57
				Bodily Pain Score	19.93
				Mental Health Score	25.45
				Vitality Score	30.12
				Physical Component Summary	34.03
				Mental Component Summary	34.50
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2398 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2399 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	51.56
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2400 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	29.88
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	30.00
				Bodily Pain Score	29.35
				Mental Health Score	23.18
				Vitality Score	25.39
				Physical Component Summary	39.37
				Mental Component Summary	31.85
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2401 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2402 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	53.79
				Reported Health Transition	4.00
				Physical Functioning Score	40.36
				Role/Physical Score	49.17
				Role Emotional Score	34.27
				Social Functioning Score	51.71
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2403 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	39.08
				Vitality Score	41.95
				Physical Component Summary	48.18
				Mental Component Summary	36.92
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2404 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2405 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	53.79
				Reported Health Transition	4.00
				Physical Functioning Score	38.27
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	41.77
				Mental Health Score	48.17
				Vitality Score	41.95

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2406 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	45.81
				Mental Component Summary	37.70
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2407 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2408 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 6	Global Health Score	53.79
				Reported Health Transition	4.00
				Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	45.90
				Vitality Score	46.69
				Physical Component Summary	53.05
				Mental Component Summary	36.40

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2409 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2410 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2411 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	46.66
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	41.77
				Mental Health Score	45.90
				Vitality Score	53.79
				Physical Component Summary	48.08
				Mental Component Summary	39.76
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2412 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2413 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2414 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 8	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	52.72
				Vitality Score	58.52
				Physical Component Summary	47.61
				Mental Component Summary	43.61
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2416 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2417 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 9	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	50.44
				Vitality Score	51.42
				Physical Component Summary	46.55
				Mental Component Summary	41.26
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2419 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2420 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	48.75
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	43.63
				Vitality Score	51.42
				Physical Component Summary	45.93
				Mental Component Summary	38.90
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2421 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2422 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2423 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	53.79
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	51.42
				Physical Component Summary	50.86
				Mental Component Summary	41.42
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2424 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2425 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2426 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	38.27
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	29.35
				Mental Health Score	30.00
				Vitality Score	34.85
				Physical Component Summary	45.36
				Mental Component Summary	25.52
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2428 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2429 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 3a	Global Health Score	50.61
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2430 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	44.56
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	54.18
				Mental Health Score	50.44
				Vitality Score	44.32
				Physical Component Summary	46.18
				Mental Component Summary	39.96
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2431 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2432 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	50.61
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2433 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	48.17
				Vitality Score	46.69
				Physical Component Summary	47.90
				Mental Component Summary	38.12
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2434 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2435 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 5	Global Health Score	55.39
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	54.18
				Mental Health Score	52.72
				Vitality Score	53.79

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2436 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	49.11
				Mental Component Summary	41.68
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2437 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2438 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	54.75
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	58.52
				Physical Component Summary	52.19
				Mental Component Summary	42.59

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2439 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2440 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2441 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	56.15
				Physical Component Summary	52.39
				Mental Component Summary	40.94
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2442 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2443 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2444 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 8	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	56.98
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	51.79
				Mental Component Summary	42.48
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2445 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2446 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2447 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 9	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	50.60
				Mental Component Summary	42.56
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2448 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2449 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2450 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	53.79
				Physical Component Summary	52.22
				Mental Component Summary	41.47
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2451 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2452 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2453 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	58.52
				Physical Component Summary	50.27
				Mental Component Summary	43.14
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2454 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2455 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2456 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	53.79
				Reported Health Transition	4.00
				Physical Functioning Score	31.97
				Role/Physical Score	27.95
				Role Emotional Score	34.27
				Social Functioning Score	46.28
				Bodily Pain Score	55.90
				Mental Health Score	43.63
				Vitality Score	51.42
				Physical Component Summary	39.47
				Mental Component Summary	43.53
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2458 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2459 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	50.61
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2460 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	48.75
				Role/Physical Score	56.24
				Role Emotional Score	34.27
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	36.81
				Vitality Score	44.32
				Physical Component Summary	51.22
				Mental Component Summary	31.58
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2461 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2462 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 4	Global Health Score	56.98
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2463 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	41.36
				Vitality Score	46.69
				Physical Component Summary	51.88
				Mental Component Summary	34.23
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2464 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2465 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	44.81
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	36.81
				Vitality Score	46.69

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2466 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	44.81
				Mental Component Summary	39.33
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2467 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2468 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 6	Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	34.27
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	53.79
				Physical Component Summary	51.60
				Mental Component Summary	43.81

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2469 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2471 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 7	Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	41.77
				Mental Health Score	54.99
				Vitality Score	60.89
				Physical Component Summary	44.47
				Mental Component Summary	45.69
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2472 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2473 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2474 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	49.01
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	34.27
				Social Functioning Score	40.85
				Bodily Pain Score	50.76
				Mental Health Score	43.63
				Vitality Score	49.05
				Physical Component Summary	47.29
				Mental Component Summary	36.30
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2475 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2476 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2477 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
			Visit 9	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	47.42
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	44.81
				Social Functioning Score	30.00
				Bodily Pain Score	62.75
				Mental Health Score	36.81
				Vitality Score	46.69
				Physical Component Summary	50.19
				Mental Component Summary	32.94
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2479 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2480 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 10	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	34.27
				Social Functioning Score	46.28
				Bodily Pain Score	55.90
				Mental Health Score	41.36
				Vitality Score	46.69
				Physical Component Summary	49.71
				Mental Component Summary	35.57
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2481 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2482 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2483 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	58.58
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	45.90
				Vitality Score	51.42
				Physical Component Summary	54.95
				Mental Component Summary	36.44
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2484 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2485 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2486 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	43.59
				Reported Health Transition	1.00
				Physical Functioning Score	29.88
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	24.21
				Mental Health Score	36.81
				Vitality Score	32.49
				Physical Component Summary	38.93
				Mental Component Summary	29.97
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2488 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2489 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A good bit of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
					Mostly false
			Visit 4	Global Health Score	47.42
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2490 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	51.61
				Mental Health Score	41.36
				Vitality Score	39.59
				Physical Component Summary	54.01
				Mental Component Summary	27.74
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2491 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2492 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 5	Global Health Score	44.23
				Reported Health Transition	3.00
				Physical Functioning Score	48.75
				Role/Physical Score	35.03
				Role Emotional Score	23.74
			Visit 5	Social Functioning Score	51.71
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2493 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 5	Mental Health Score	43.63
				Vitality Score	46.69
				Physical Component Summary	47.17
				Mental Component Summary	35.13
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2495 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 6	Global Health Score	45.82
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	45.90
				Vitality Score	49.05

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2496 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	49.34
				Mental Component Summary	37.33
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2497 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2498 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	49.01
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	34.27
				Social Functioning Score	40.85
				Bodily Pain Score	62.75
				Mental Health Score	27.73
				Vitality Score	46.69
				Physical Component Summary	53.65
				Mental Component Summary	27.33

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2499 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2501 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	47.42
				Reported Health Transition	2.00
				Physical Functioning Score	46.66
				Role/Physical Score	49.17
				Role Emotional Score	34.27
				Social Functioning Score	57.14
				Bodily Pain Score	37.48
				Mental Health Score	34.54
				Vitality Score	39.59
				Physical Component Summary	47.29
				Mental Component Summary	35.14
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2502 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2503 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2504 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 9	Global Health Score	44.23
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	34.27
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	27.73
				Vitality Score	39.59
				Physical Component Summary	44.23
				Mental Component Summary	28.19
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2506 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2507 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 10	Global Health Score	42.63
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	43.63
				Vitality Score	41.95
				Physical Component Summary	51.79
				Mental Component Summary	30.38
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2509 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2510 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 11	Global Health Score	47.42
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	34.27
				Social Functioning Score	46.28
				Bodily Pain Score	51.61
				Mental Health Score	34.54
				Vitality Score	46.69
				Physical Component Summary	47.28
				Mental Component Summary	33.69
		In general, would you say your health is:	Very good		
		Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago		
		Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little		
		Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all		
		Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2511 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2512 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2513 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	45.18
				Reported Health Transition	1.00
				Physical Functioning Score	42.46
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	30.00
				Bodily Pain Score	25.07
				Mental Health Score	39.08
				Vitality Score	30.12
				Physical Component Summary	44.45
				Mental Component Summary	24.59
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2515 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2516 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 3a	Global Health Score	55.39
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2517 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	49.05
				Physical Component Summary	49.02
				Mental Component Summary	41.50
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2518 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2519 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	58.58
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	62.75

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2520 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	57.26
				Vitality Score	65.62
				Physical Component Summary	52.85
				Mental Component Summary	45.30
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2521 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2522 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 5	Global Health Score	56.35
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	59.53
				Vitality Score	63.25

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2523 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	51.73
				Mental Component Summary	45.89
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2524 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2525 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	60.89
				Physical Component Summary	52.82
				Mental Component Summary	43.11

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2526 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2528 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
				Global Health Score	56.98
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	54.99
				Vitality Score	58.52
				Physical Component Summary	52.75
				Mental Component Summary	42.55
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2529 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2530 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2531 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	47.42
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	47.23
				Mental Component Summary	43.30
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2532 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2533 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2534 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	56.98
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	57.26
				Vitality Score	60.89
				Physical Component Summary	52.32
				Mental Component Summary	44.22
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2535 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2536 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2537 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	42.00
				Reported Health Transition	2.00
				Physical Functioning Score	48.75
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	41.77
				Mental Health Score	52.72
				Vitality Score	46.69
				Physical Component Summary	41.48
				Mental Component Summary	40.54
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2538 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2539 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2540 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 11	Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	60.89
				Physical Component Summary	48.56
				Mental Component Summary	44.34
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2541 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2542 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2543 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	53.79
				Reported Health Transition	1.00
				Physical Functioning Score	23.58
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	35.42
				Bodily Pain Score	25.07
				Mental Health Score	43.63
				Vitality Score	39.59
				Physical Component Summary	31.75
				Mental Component Summary	48.41
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2545 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2546 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	45.18
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2547 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	40.36
				Role/Physical Score	42.10
				Role Emotional Score	34.27
				Social Functioning Score	51.71
				Bodily Pain Score	37.48
				Mental Health Score	39.08
				Vitality Score	44.32
				Physical Component Summary	40.76
				Mental Component Summary	39.36
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2548 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2549 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	45.18
				Reported Health Transition	2.00
				Physical Functioning Score	34.07
				Role/Physical Score	56.24
				Role Emotional Score	23.74
			Visit 5	Social Functioning Score	51.71
				Bodily Pain Score	33.20

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2550 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 5	Mental Health Score	39.08
				Vitality Score	39.59
				Physical Component Summary	43.58
				Mental Component Summary	33.79
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2551 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2552 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 6	Global Health Score	44.23
				Reported Health Transition	2.00
				Physical Functioning Score	42.46
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	37.48
				Mental Health Score	41.36
				Vitality Score	41.95

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2553 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	42.86
				Mental Component Summary	34.87
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2554 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2555 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	40.40
				Reported Health Transition	2.00
				Physical Functioning Score	46.66
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	33.20
				Mental Health Score	39.08
				Vitality Score	44.32
				Physical Component Summary	47.86
				Mental Component Summary	32.09

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2556 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2558 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 8	Global Health Score	37.85
				Reported Health Transition	3.00
				Physical Functioning Score	48.75
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	42.19
				Mental Health Score	48.17
				Vitality Score	41.95
				Physical Component Summary	48.86
				Mental Component Summary	36.09
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2559 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2560 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2561 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 9	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	44.23
				Reported Health Transition	3.00
				Physical Functioning Score	42.46
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	42.19
				Mental Health Score	39.08
				Vitality Score	44.32
				Physical Component Summary	39.96
				Mental Component Summary	35.61
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2563 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2564 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 10	Global Health Score	47.42
				Reported Health Transition	3.00
				Physical Functioning Score	46.66
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	37.48
				Mental Health Score	43.63
				Vitality Score	44.32
				Physical Component Summary	49.93
				Mental Component Summary	35.23
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2565 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2566 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2567 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 11	Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	44.56
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	54.18
				Mental Health Score	36.81
				Vitality Score	44.32
				Physical Component Summary	46.39
				Mental Component Summary	31.32
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2568 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2569 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2570 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
10-1001	ES	Baseline	(Visit 2a)	Global Health Score	42.00
				Reported Health Transition	1.00
				Physical Functioning Score	19.39
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	13.71
				Bodily Pain Score	19.93
				Mental Health Score	11.82
				Vitality Score	32.49
				Physical Component Summary	32.37
				Mental Component Summary	27.10
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2572 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
10-1001	ES	Baseline	(Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2573 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
10-1001	ES	Baseline (Visit 2a)		For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	All of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2574 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	42.00
				Reported Health Transition	1.00
				Physical Functioning Score	25.68
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	19.93
				Mental Health Score	36.81
				Vitality Score	25.39
				Physical Component Summary	35.19
				Mental Component Summary	29.70
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2575 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2576 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 3a	Global Health Score	42.63
				Reported Health Transition	3.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2577 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	42.19
				Mental Health Score	50.44
				Vitality Score	44.32
				Physical Component Summary	46.22
				Mental Component Summary	33.77
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2578 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2579 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 4	Global Health Score	47.42
				Reported Health Transition	4.00
				Physical Functioning Score	48.75
				Role/Physical Score	49.17
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	51.71
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2580 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	52.72
				Vitality Score	44.32
				Physical Component Summary	49.23
				Mental Component Summary	37.70
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2581 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2582 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	49.01
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	51.42

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2583 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	50.17
				Mental Component Summary	40.39
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2584 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2585 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	42.00
				Reported Health Transition	4.00
				Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	37.48
				Mental Health Score	43.63
				Vitality Score	37.22
				Physical Component Summary	47.60
				Mental Component Summary	29.75

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2586 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2587 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2588 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 7	Global Health Score	47.42
				Reported Health Transition	5.00
				Physical Functioning Score	50.85
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	45.90
				Vitality Score	41.95
				Physical Component Summary	53.99
				Mental Component Summary	33.93
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2589 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2590 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2591 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	40.40
				Reported Health Transition	2.00
				Physical Functioning Score	42.46
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	30.00
				Bodily Pain Score	33.20
				Mental Health Score	39.08
				Vitality Score	30.12
				Physical Component Summary	41.79
				Mental Component Summary	33.02
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2593 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2594 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 9	Global Health Score	35.62
				Reported Health Transition	2.00
				Physical Functioning Score	42.46
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	29.35
				Mental Health Score	41.36
				Vitality Score	37.22
				Physical Component Summary	43.04
				Mental Component Summary	30.02
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2596 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2597 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 10	Global Health Score	35.62
				Reported Health Transition	2.00
				Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	24.57
				Bodily Pain Score	29.35
				Mental Health Score	27.73
				Vitality Score	25.39
				Physical Component Summary	38.87
				Mental Component Summary	30.43
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2598 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2599 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2600 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 11	Global Health Score	32.43
				Reported Health Transition	2.00
				Physical Functioning Score	34.07
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	30.00
				Bodily Pain Score	29.35
				Mental Health Score	30.00
				Vitality Score	32.49
				Physical Component Summary	41.14
				Mental Component Summary	22.45
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2601 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2602 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2603 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	38.81
				Reported Health Transition	1.00
				Physical Functioning Score	15.19
				Role/Physical Score	56.24
				Role Emotional Score	34.27
				Social Functioning Score	24.57
				Bodily Pain Score	19.93
				Mental Health Score	30.00
				Vitality Score	41.95
				Physical Component Summary	30.03
				Mental Component Summary	32.95
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2605 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2606 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	All of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	49.01
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2607 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	54.99
				Vitality Score	56.15
				Physical Component Summary	46.74
				Mental Component Summary	43.75
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2609 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	42.63
				Reported Health Transition	2.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	55.90

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2610 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	52.72
				Vitality Score	46.69
				Physical Component Summary	45.38
				Mental Component Summary	40.52
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2611 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2612 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 5	Global Health Score	44.23
				Reported Health Transition	2.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	34.54
				Vitality Score	39.59

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2613 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	51.36
				Mental Component Summary	29.03
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2614 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2615 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	47.42
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	48.17
				Vitality Score	46.69
				Physical Component Summary	49.35
				Mental Component Summary	37.28

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2616 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2617 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2618 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	46.78
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	41.36
				Vitality Score	44.32
				Physical Component Summary	50.63
				Mental Component Summary	33.42
				In general, would you say your health is:	Excellent

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2619 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2620 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2621 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	47.42
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	41.36
				Vitality Score	37.22
				Physical Component Summary	50.58
				Mental Component Summary	31.74
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2623 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2624 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	50.61
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	62.75
				Mental Health Score	39.08
				Vitality Score	34.85
				Physical Component Summary	54.03
				Mental Component Summary	27.90
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2626 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2627 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	47.42
				Reported Health Transition	2.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	39.08
				Vitality Score	32.49
				Physical Component Summary	50.95
				Mental Component Summary	29.52
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2628 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2629 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2630 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	44.23
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	55.90
				Mental Health Score	39.08
				Vitality Score	25.39
				Physical Component Summary	50.03
				Mental Component Summary	24.98
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2631 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2632 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2633 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	36.26
				Reported Health Transition	1.00
				Physical Functioning Score	15.19
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	13.71
				Bodily Pain Score	19.93
				Mental Health Score	18.64
				Vitality Score	18.29
				Physical Component Summary	27.25
				Mental Component Summary	28.13
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2635 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2636 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	All of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 4	Global Health Score	36.26
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2637 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	38.27
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	24.57
				Bodily Pain Score	37.48
				Mental Health Score	25.45
				Vitality Score	23.02
				Physical Component Summary	41.16
				Mental Component Summary	28.45
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2638 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2639 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 5	Global Health Score	39.44
				Reported Health Transition	3.00
				Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	55.34
			Visit 5	Social Functioning Score	35.42
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2640 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 5	Mental Health Score	30.00
				Vitality Score	30.12
				Physical Component Summary	46.45
				Mental Component Summary	33.34
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2642 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 6	Global Health Score	42.63
				Reported Health Transition	5.00
				Physical Functioning Score	48.75
				Role/Physical Score	27.95
				Role Emotional Score	44.81
				Social Functioning Score	35.42
				Bodily Pain Score	51.61
				Mental Health Score	30.00
				Vitality Score	30.12

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2643 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	42.89
				Mental Component Summary	30.28
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2644 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2645 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
				Global Health Score	38.81
				Reported Health Transition	4.00
				Physical Functioning Score	42.46
				Role/Physical Score	27.95
				Role Emotional Score	55.34
				Social Functioning Score	40.85
				Bodily Pain Score	41.77
				Mental Health Score	43.63
				Vitality Score	25.39
				Physical Component Summary	30.93
				Mental Component Summary	44.28

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2646 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2648 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 8	Global Health Score	39.44
				Reported Health Transition	3.00
				Physical Functioning Score	42.46
				Role/Physical Score	49.17
				Role Emotional Score	55.34
				Social Functioning Score	30.00
				Bodily Pain Score	37.48
				Mental Health Score	41.36
				Vitality Score	27.75
				Physical Component Summary	37.84
				Mental Component Summary	38.61
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2649 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2650 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2651 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 9	Global Health Score	38.81
				Reported Health Transition	2.00
				Physical Functioning Score	34.07
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	24.57
				Bodily Pain Score	29.35
				Mental Health Score	34.54
				Vitality Score	23.02
				Physical Component Summary	41.50
				Mental Component Summary	20.87
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2653 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2654 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 10	Global Health Score	42.00
				Reported Health Transition	2.00
				Physical Functioning Score	27.78
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	30.00
				Bodily Pain Score	29.35
				Mental Health Score	36.81
				Vitality Score	18.29
				Physical Component Summary	32.88
				Mental Component Summary	37.43
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2656 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2657 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 11	Global Health Score	35.62
				Reported Health Transition	2.00
				Physical Functioning Score	25.68
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	13.71
				Bodily Pain Score	25.07
				Mental Health Score	30.00
				Vitality Score	18.29
				Physical Component Summary	30.66
				Mental Component Summary	30.74
		In general, would you say your health is:	Fair		
		Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago		
		Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little		
		Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little		
		Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot		

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2658 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2659 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2660 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	47.42
				Reported Health Transition	2.00
				Physical Functioning Score	48.75
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	41.77
				Mental Health Score	41.36
				Vitality Score	41.95
				Physical Component Summary	47.68
				Mental Component Summary	32.95
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2662 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2663 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	50.61
				Reported Health Transition	4.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2664 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	46.66
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	51.42
				Physical Component Summary	47.51
				Mental Component Summary	41.19
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2665 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2666 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	50.85
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2667 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	48.17
				Vitality Score	49.05
				Physical Component Summary	49.33
				Mental Component Summary	38.59
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2668 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2669 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	46.66
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	45.90
				Vitality Score	46.69

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2670 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	48.78
				Mental Component Summary	37.84
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2671 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2672 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	41.36
				Vitality Score	46.69
				Physical Component Summary	53.34
				Mental Component Summary	33.71

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2673 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2675 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	43.63
				Vitality Score	46.69
				Physical Component Summary	51.95
				Mental Component Summary	35.29
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2676 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2677 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2678 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	43.63
				Vitality Score	49.05
				Physical Component Summary	52.90
				Mental Component Summary	35.37
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2679 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2680 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2681 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	47.42
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	45.90
				Vitality Score	46.69
				Physical Component Summary	51.14
				Mental Component Summary	35.99
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2683 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2684 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	44.32
				Physical Component Summary	50.47
				Mental Component Summary	37.61
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2685 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2686 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2687 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	49.01
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	51.42
				Physical Component Summary	50.67
				Mental Component Summary	39.28
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2688 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2689 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2690 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	53.79
				Reported Health Transition	5.00
				Physical Functioning Score	21.49
				Role/Physical Score	56.24
				Role Emotional Score	34.27
				Social Functioning Score	40.85
				Bodily Pain Score	19.93
				Mental Health Score	43.63
				Vitality Score	44.32
				Physical Component Summary	33.37
				Mental Component Summary	42.82
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2692 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2693 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 3a	Global Health Score	53.79
				Reported Health Transition	5.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2694 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	48.75
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	33.63
				Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	39.45
				Mental Component Summary	44.59
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2695 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2696 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 4	Global Health Score	52.20
				Reported Health Transition	4.00
				Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	46.28
				Bodily Pain Score	25.07

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2697 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	48.17
				Vitality Score	46.69
				Physical Component Summary	39.37
				Mental Component Summary	50.41
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2698 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2699 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	47.42
				Reported Health Transition	5.00
				Physical Functioning Score	52.95
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	42.19
				Mental Health Score	45.90
				Vitality Score	46.69

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2700 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	48.77
				Mental Component Summary	33.81
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2701 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2702 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 6	Global Health Score	49.97
				Reported Health Transition	3.00
				Physical Functioning Score	34.07
				Role/Physical Score	49.17
				Role Emotional Score	55.34
				Social Functioning Score	57.14
				Bodily Pain Score	24.21
				Mental Health Score	20.91
				Vitality Score	30.12
				Physical Component Summary	37.07
				Mental Component Summary	39.59

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2703 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2705 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	35.62
				Reported Health Transition	1.00
				Physical Functioning Score	42.46
				Role/Physical Score	49.17
				Role Emotional Score	55.34
				Social Functioning Score	24.57
				Bodily Pain Score	37.48
				Mental Health Score	23.18
				Vitality Score	30.12
				Physical Component Summary	41.00
				Mental Component Summary	28.94
				In general, would you say your health is:	Fair

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2706 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2707 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2708 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
			Visit 8	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
				Global Health Score	37.21
				Reported Health Transition	2.00
				Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	24.57
				Bodily Pain Score	37.48
				Mental Health Score	32.27
				Vitality Score	46.69
				Physical Component Summary	43.24
				Mental Component Summary	35.87
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2710 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Quite a bit
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2711 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 9	Global Health Score	34.02
				Reported Health Transition	1.00
				Physical Functioning Score	23.58
				Role/Physical Score	56.24
				Role Emotional Score	55.34
				Social Functioning Score	13.71
				Bodily Pain Score	25.07
				Mental Health Score	16.37
				Vitality Score	25.39
				Physical Component Summary	32.59
				Mental Component Summary	26.30
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2713 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A good bit of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2714 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	All of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 10	Global Health Score	40.40
				Reported Health Transition	2.00
				Physical Functioning Score	38.27
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	30.00
				Bodily Pain Score	29.35
				Mental Health Score	45.90
				Vitality Score	37.22
				Physical Component Summary	37.49
				Mental Component Summary	39.34
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2715 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2716 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2717 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 11	Global Health Score	44.23
				Reported Health Transition	4.00
				Physical Functioning Score	42.46
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	30.00
				Bodily Pain Score	46.48
				Mental Health Score	36.81
				Vitality Score	51.42
				Physical Component Summary	47.15
				Mental Component Summary	28.18
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2718 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Extremely
				How much bodily pain have you had during the past 4 weeks?	Mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2719 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2720 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	42.63
				Reported Health Transition	2.00
				Physical Functioning Score	21.49
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	19.93
				Mental Health Score	41.36
				Vitality Score	34.85
				Physical Component Summary	32.72
				Mental Component Summary	39.47
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2722 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a lot
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2723 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false
			Visit 3a	Global Health Score	49.01
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2724 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	46.66
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	39.08
				Vitality Score	51.42
				Physical Component Summary	51.97
				Mental Component Summary	42.44
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2725 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2726 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	None of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 4	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	40.36
				Role/Physical Score	56.24
				Role Emotional Score	23.74
			Visit 4	Social Functioning Score	57.14
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2727 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	39.08
				Vitality Score	41.95
				Physical Component Summary	51.85
				Mental Component Summary	32.98
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2728 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2729 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	45.82
				Reported Health Transition	5.00
				Physical Functioning Score	38.27
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	46.48
				Mental Health Score	45.90
				Vitality Score	44.32

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2730 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	45.93
				Mental Component Summary	35.36
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2731 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2732 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	40.36
				Role/Physical Score	49.17
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	41.77
				Mental Health Score	45.90
				Vitality Score	46.69
				Physical Component Summary	46.62
				Mental Component Summary	34.36

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2733 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2735 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	50.61
				Reported Health Transition	5.00
				Physical Functioning Score	44.56
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	45.90
				Vitality Score	53.79
				Physical Component Summary	45.01
				Mental Component Summary	40.73
				In general, would you say your health is:	Good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2736 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2737 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2738 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	50.61
				Reported Health Transition	4.00
				Physical Functioning Score	42.46
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	42.19
				Mental Health Score	30.00
				Vitality Score	49.05
				Physical Component Summary	46.18
				Mental Component Summary	31.33
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2740 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2741 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	45.82
				Reported Health Transition	2.00
				Physical Functioning Score	40.83
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	37.48
				Mental Health Score	45.90
				Vitality Score	39.59
				Physical Component Summary	46.50
				Mental Component Summary	33.66
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2743 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2744 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 10	Global Health Score	52.20
				Reported Health Transition	4.00
				Physical Functioning Score	46.66
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	41.77
				Mental Health Score	45.90
				Vitality Score	39.59
				Physical Component Summary	44.39
				Mental Component Summary	37.34
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2745 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2746 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2747 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	46.66
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	41.77
				Mental Health Score	48.17
				Vitality Score	49.05
				Physical Component Summary	41.28
				Mental Component Summary	41.57
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2748 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Moderate

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2749 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2750 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	47.42
				Reported Health Transition	2.00
				Physical Functioning Score	23.58
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	19.93
				Mental Health Score	45.90
				Vitality Score	44.32
				Physical Component Summary	34.15
				Mental Component Summary	40.43
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a little

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2752 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2753 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 3a	Global Health Score	47.42
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2754 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 3a	Physical Functioning Score	46.66
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	47.33
				Mental Health Score	50.44
				Vitality Score	41.95
				Physical Component Summary	51.57
				Mental Component Summary	34.11
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2755 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2756 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 4	Global Health Score	47.42
				Reported Health Transition	4.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2757 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 4	Mental Health Score	45.90
				Vitality Score	46.69
				Physical Component Summary	45.08
				Mental Component Summary	38.05
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2758 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2759 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 5	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	48.17
				Vitality Score	49.05

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2760 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 5	Physical Component Summary	48.44
				Mental Component Summary	38.75
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2761 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2762 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	48.17
				Vitality Score	53.79
				Physical Component Summary	49.86
				Mental Component Summary	39.35

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2763 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2764 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2765 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	51.61
				Mental Health Score	50.44
				Vitality Score	49.05
				Physical Component Summary	47.86
				Mental Component Summary	39.76
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2766 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2767 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2768 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
			Visit 8	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	50.76
				Mental Health Score	50.44
				Vitality Score	51.42
				Physical Component Summary	46.77
				Mental Component Summary	40.88
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2769 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2770 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2771 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 9	Global Health Score	52.20
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	45.90
				Vitality Score	49.05
				Physical Component Summary	51.12
				Mental Component Summary	36.65
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2773 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2774 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	50.61
				Reported Health Transition	3.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	45.90
				Vitality Score	44.32
				Physical Component Summary	49.69
				Mental Component Summary	36.05
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2775 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2776 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2777 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	47.42
				Reported Health Transition	2.00
				Physical Functioning Score	52.95
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	50.44
				Vitality Score	51.42
				Physical Component Summary	44.22
				Mental Component Summary	41.37
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2778 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2779 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2780 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	50.61
				Reported Health Transition	1.00
				Physical Functioning Score	44.56
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	29.35
				Mental Health Score	52.72
				Vitality Score	41.95
				Physical Component Summary	45.26
				Mental Component Summary	37.39
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2782 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Quite a bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2783 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
			Visit 4	Global Health Score	56.98
				Reported Health Transition	4.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2784 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 4	Physical Functioning Score	52.95
				Role/Physical Score	42.10
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	48.17
				Vitality Score	46.69
				Physical Component Summary	57.10
				Mental Component Summary	35.68
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2785 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 4	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2786 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 5	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	52.95
				Role/Physical Score	35.03
				Role Emotional Score	23.74
			Visit 5	Social Functioning Score	57.14
				Bodily Pain Score	54.18

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2787 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 5	Mental Health Score	50.44
				Vitality Score	46.69
				Physical Component Summary	51.00
				Mental Component Summary	38.51
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 5	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2789 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 6	Global Health Score	56.98
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	50.44
				Vitality Score	44.32

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2790 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 6	Physical Component Summary	53.35
				Mental Component Summary	37.01
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2791 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 6	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2792 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
			Visit 7	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	52.20
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	56.24
				Role Emotional Score	23.74
				Social Functioning Score	35.42
				Bodily Pain Score	37.48
				Mental Health Score	39.08
				Vitality Score	27.75
				Physical Component Summary	56.26
				Mental Component Summary	20.80

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2793 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 7	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 7	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Moderately
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2795 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Most of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 8	Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	51.42
				Physical Component Summary	52.65
				Mental Component Summary	39.80
				In general, would you say your health is:	Very good

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2796 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 8	Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2797 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 8	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2798 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
			Visit 9	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	55.39
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	52.72
				Vitality Score	49.05
				Physical Component Summary	52.58
				Mental Component Summary	39.25
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2799 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2800 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 9	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2801 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 9	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
			Visit 10	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
				Global Health Score	56.98
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	48.17
				Vitality Score	44.32
				Physical Component Summary	53.85
				Mental Component Summary	35.90
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2803 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 10	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2804 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 11	Global Health Score	53.79
				Reported Health Transition	2.00
				Physical Functioning Score	50.85
				Role/Physical Score	35.03
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	46.48
				Mental Health Score	48.17
				Vitality Score	39.59
				Physical Component Summary	47.56
				Mental Component Summary	37.00
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2805 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2806 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 11	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2807 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Definitely false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Global Health Score	37.21
				Reported Health Transition	1.00
				Physical Functioning Score	25.68
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	40.85
				Bodily Pain Score	19.93
				Mental Health Score	34.54
				Vitality Score	37.22
				Physical Component Summary	30.79
				Mental Component Summary	40.60
				In general, would you say your health is:	Poor
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2809 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very severe
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Extremely
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2810 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Most of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly true
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 3a	Global Health Score	42.63
				Reported Health Transition	2.00

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2811 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 3a	Physical Functioning Score	48.75
				Role/Physical Score	56.24
				Role Emotional Score	44.81
				Social Functioning Score	35.42
				Bodily Pain Score	51.61
				Mental Health Score	27.73
				Vitality Score	39.59
				Physical Component Summary	53.60
				Mental Component Summary	27.92
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2812 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 3a	have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	Yes
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	Yes
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	Yes
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	Yes
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2813 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 3a	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 4	Global Health Score	44.23
				Reported Health Transition	4.00
				Physical Functioning Score	48.75
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	40.85
				Bodily Pain Score	51.61

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2814 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 4	Mental Health Score	30.00
				Vitality Score	41.95
				Physical Component Summary	47.64
				Mental Component Summary	25.35
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2815 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 4	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2816 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 4	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 5	Global Health Score	42.63
				Reported Health Transition	4.00
				Physical Functioning Score	55.05
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	46.28
				Bodily Pain Score	51.61
				Mental Health Score	27.73
				Vitality Score	34.85

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2817 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 5	Physical Component Summary	50.16
				Mental Component Summary	22.61
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a little
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2818 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 5	During past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your physical health?Were limited in the kind of work or other activities past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2819 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 5	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
			Visit 6	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	45.82
				Reported Health Transition	5.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	51.71
				Bodily Pain Score	62.75
				Mental Health Score	25.45
				Vitality Score	37.22
				Physical Component Summary	55.91
				Mental Component Summary	21.91

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2820 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 6	In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	Much better than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 6	past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2822 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 6	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 7	Global Health Score	38.81
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	34.27
				Social Functioning Score	46.28
				Bodily Pain Score	41.77
				Mental Health Score	25.45
				Vitality Score	32.49
				Physical Component Summary	45.38
				Mental Component Summary	26.06
				In general, would you say your health is:	Fair

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2823 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 7	Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2824 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 7	have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Slightly
				How much bodily pain have you had during the past 4 weeks?	Moderate
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	A little bit
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A good bit of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2825 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 7	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A good bit of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	A little of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly false
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
			Visit 8	How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly false
				Global Health Score	44.23
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	44.81
				Social Functioning Score	35.42
				Bodily Pain Score	55.90
				Mental Health Score	18.64
				Vitality Score	37.22
				Physical Component Summary	50.92
				Mental Component Summary	24.06
				In general, would you say your health is:	Good
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 8	Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2827 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 8	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes
				past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	Yes
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Moderately
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Most of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2828 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 8	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	Some of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Don't know
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly true
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Don't know
			Visit 9	Global Health Score	49.01
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	34.27
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	34.54
				Vitality Score	46.69
				Physical Component Summary	50.74
				Mental Component Summary	35.20
				In general, would you say your health is:	Very good
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 9	Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	Yes

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2830 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 9	past 4 weeks,have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems?Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	Some of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2831 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 9	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Don't know
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Don't know
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true
			Visit 10	Global Health Score	54.75
				Reported Health Transition	4.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	45.90
				Vitality Score	46.69
				Physical Component Summary	53.86
				Mental Component Summary	35.39
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	Somewhat better now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2832 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 10	Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2833 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 10	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	Some of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2834 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 10	How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely true
			Visit 11	Global Health Score	53.16
				Reported Health Transition	3.00
				Physical Functioning Score	57.14
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	62.75
				Mental Health Score	45.90
				Vitality Score	49.05
				Physical Component Summary	53.53
				Mental Component Summary	35.97
				In general, would you say your health is:	Excellent
				Compared to one year ago, how would you rate your health in general now?	About the same as one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	NO, NOT limited at all

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2835 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 11	Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking several blocks	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Walking one block	NO, NOT limited at all
				Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	NO, NOT limited at all
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didn't do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	None

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2836 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 11	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	A little of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	A good bit of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	Some of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Mostly true

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2837 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 11	How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Mostly false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Mostly true

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1305	NDisc plus	ES/SAF	Baseline (Visit 2a)	Global Health Score	46.78
				Reported Health Transition	1.00
				Physical Functioning Score	17.29
				Role/Physical Score	27.95
				Role Emotional Score	23.74
				Social Functioning Score	57.14
				Bodily Pain Score	55.90
				Mental Health Score	57.26
				Vitality Score	60.89
				Physical Component Summary	30.70
				Mental Component Summary	54.21
				In general, would you say your health is:	Fair
				Compared to one year ago, how would you rate your health in general now?	Much worse now than one year ago
				Does your health now limit you in these activities? If so, how much? Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Lifting or carrying groceries	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing several flights of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Climbing one flight of stairs	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Bending, kneeling, or stooping	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking more than a mile	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking several blocks	YES, limited a lot
				Does your health now limit you in these activities? If so, how much? Walking one block	YES, limited a lot

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2839 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1305	NDisc plus	ES/SAF	Baseline (Visit 2a)	Does your health now limit you in these activities? If so, how much? Bathing or dressing yourself	YES, limited a little
				have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Accomplished less than you would like	No
				During past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Were limited in the kind of work or other activities	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Had difficulty performing the work or other activities	No
				have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Cut down on the amount of time you spent on work or other activities	No
				During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Accomplished less than you would like	No
				past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your emotional problems? Didnt do work or other activities as carefully as usual	No
				During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Not at all
				How much bodily pain have you had during the past 4 weeks?	Very mild
				During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	Not at all
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you feel full of pep?	All of the time

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2840 of 2841

-continued on next page-

Listing 16.2.2.5: SF-36 Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1305	NDisc plus	ES/SAF	Baseline (Visit 2a)	For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you been a very nervous person?	None of the time
				How much of the time during the past 4 weeks.....Have you felt so down in the dumps that nothing could cheer you up?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you felt calm and peaceful?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Did you have a lot of energy?	All of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.....Have you felt downhearted and blue?	None of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks Did you feel worn out?	A little of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Have you been a happy person?	Most of the time
				For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.... Did you feel tired?	A little of the time
				During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?	None of the time
				How TRUE or FALSE is each of the following statements for you?... I seem to get sick a little easier than other people	Mostly false
				How TRUE or FALSE is each of the following statements for you?... I am as healthy as anybody I know	Definitely true
				How TRUE or FALSE is each of the following statements for you?...I expect my health to get worse	Definitely false
				How TRUE or FALSE is each of the following statements for you?... My health is excellent	Definitely false

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set

Norm-based (50, 10) z-scores (based on 1998 general US population standard values) are displayed.

Clinipace: 14DEC21 / 7:42 / l_sf36.lst / l_sf36.sas

Page 2841 of 2841

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	74
				EQ-5D-3L Index Utility Score	0.786
			Visit 3a	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	54
				EQ-5D-3L Index Utility Score	0.786
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	40
				EQ-5D-3L Index Utility Score	0.786
			Visit 5	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	0.172
			Visit 6	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	68
				EQ-5D-3L Index Utility Score	0.697

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0103	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	45
				EQ-5D-3L Index Utility Score	0.697
			Visit 8	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	21
				EQ-5D-3L Index Utility Score	0.172
			Visit 9	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am extremely anxious or depressed
				EQ VAS	21
				EQ-5D-3L Index Utility Score	-0.215
			Visit 10	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	38
				EQ-5D-3L Index Utility Score	0.697
			Visit 11	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	37
				EQ-5D-3L Index Utility Score	0.697

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.886
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.787

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0104	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	96
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.886
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.886
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	92
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	86
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0106	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	74
				EQ-5D-3L Index Utility Score	0.785
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	19
				EQ-5D-3L Index Utility Score	-0.150
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.999
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0107	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	46
				EQ-5D-3L Index Utility Score	0.785
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	81
				EQ-5D-3L Index Utility Score	0.886
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	82
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	83
				EQ-5D-3L Index Utility Score	0.886
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	86
				EQ-5D-3L Index Utility Score	0.886

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0108	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.886
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	88
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	91
				EQ-5D-3L Index Utility Score	0.999
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	86
				EQ-5D-3L Index Utility Score	0.999
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.886

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	54
				EQ-5D-3L Index Utility Score	-0.150
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	0.999
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.899
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0110	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.785
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	71
				EQ-5D-3L Index Utility Score	0.786
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	0.887
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0111	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0112	NDisc basic	ES/SAF	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	25
				EQ-5D-3L Index Utility Score	0.785

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.786
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0113	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	0.786
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000
			Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	40
				EQ-5D-3L Index Utility Score	-0.149
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.887
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0114	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.697
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.886
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0115	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	96
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	96
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0116	NDisc basic	ES/SAF	Baseline (Visit 2a)	Mobility	I am confined to bed
				Self-Care	I am unable to wash or dress myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	49
				EQ-5D-3L Index Utility Score	-0.586

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	68
				EQ-5D-3L Index Utility Score	0.886
			Visit 3a	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	40
				EQ-5D-3L Index Utility Score	0.786
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	50
				EQ-5D-3L Index Utility Score	0.698
			Visit 5	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ-5D-3L Index Utility Score	0.698
			Visit 6	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	48
				EQ-5D-3L Index Utility Score	0.786
			Visit 7	Mobility	I have some problems in walking about

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0118	NDisc plus	ES/SAF/FAS	Visit 7	Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	78
				EQ-5D-3L Index Utility Score	0.698
			Visit 8	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	28
				EQ-5D-3L Index Utility Score	-0.150
			Visit 9	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	27
				EQ-5D-3L Index Utility Score	0.697
			Visit 10	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	28
				EQ-5D-3L Index Utility Score	0.697
			Visit 11	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	37
				EQ-5D-3L Index Utility Score	0.463

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	10
				EQ-5D-3L Index Utility Score	0.376
			Visit 3a	Mobility	
				Self-Care	
				Usual Activities	
				Pain/Discomfort	
				Anxiety/Depression	
				EQ VAS	94
				EQ-5D-3L Index Utility Score	
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	96
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0119	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	0.887
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	68
				EQ-5D-3L Index Utility Score	0.786
			Visit 10	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	49
				EQ-5D-3L Index Utility Score	0.786
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ-5D-3L Index Utility Score	0.886

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.463
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	0.999
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	0.886
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0121	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.786
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	0.999
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0122	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	0.887
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	44
				EQ-5D-3L Index Utility Score	0.697
			Visit 3a	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.697
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	39
				EQ-5D-3L Index Utility Score	0.697
			Visit 5	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	49
				EQ-5D-3L Index Utility Score	0.697
			Visit 6	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	49
				EQ-5D-3L Index Utility Score	0.463

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0123	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	59
				EQ-5D-3L Index Utility Score	0.697
			Visit 8	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ-5D-3L Index Utility Score	0.697
			Visit 9	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	50
				EQ-5D-3L Index Utility Score	0.785
			Visit 10	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	19
				EQ-5D-3L Index Utility Score	0.172

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0124	NDisc plus	ES/SAF	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.885

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	76
				EQ-5D-3L Index Utility Score	0.698
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	83
				EQ-5D-3L Index Utility Score	0.999
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	93
				EQ-5D-3L Index Utility Score	1.000
			Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0125	SC	ES/SAF/FAS	Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	40
				EQ-5D-3L Index Utility Score	0.361
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	81
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	52
				EQ-5D-3L Index Utility Score	0.887
			Baseline (Visit 2a)	Mobility	I am confined to bed
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	-0.702
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	10
				EQ-5D-3L Index Utility Score	0.886
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	35
				EQ-5D-3L Index Utility Score	0.786
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	59
				EQ-5D-3L Index Utility Score	0.885

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0126	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	91
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	93
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.464
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	88
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	0.887
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	0.886
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0127	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	86
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.786
			Visit 10	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.786
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	68
				EQ-5D-3L Index Utility Score	0.786
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	81
				EQ-5D-3L Index Utility Score	0.887
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	88
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0128	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	74
				EQ-5D-3L Index Utility Score	0.887
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	88
				EQ-5D-3L Index Utility Score	0.886
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	62
				EQ-5D-3L Index Utility Score	0.698
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.787
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	86
				EQ-5D-3L Index Utility Score	0.887
			Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0129	SC	ES/SAF/FAS	Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	86
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	63
				EQ-5D-3L Index Utility Score	0.787
			Visit 10	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	62
				EQ-5D-3L Index Utility Score	0.786
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.886
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0130	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	40
				EQ-5D-3L Index Utility Score	0.172
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	74
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	86
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	88
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0131	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	88
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.785
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0132	SC	ES/SAF/FAS	Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	91
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0133	NDisc plus	ES/SAF	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.260

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0134	NDisc basic	ES/SAF	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	28
				EQ-5D-3L Index Utility Score	0.786

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	65
				EQ-5D-3L Index Utility Score	0.887
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	78
				EQ-5D-3L Index Utility Score	0.887
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	0.887
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	83
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0135	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	91
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.885
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	72
				EQ-5D-3L Index Utility Score	0.886
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.786
			Visit 3a	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	68
				EQ-5D-3L Index Utility Score	0.786
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.786
			Visit 5	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.786
			Visit 6	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.786

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0136	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.262
			Visit 8	Mobility	
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	60
			Visit 9	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	60
			Visit 10	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	59
			Visit 11	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	0.785

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.886
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	0.999
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	0.887
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.886
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0137	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	91
				EQ-5D-3L Index Utility Score	0.886
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	88
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	96
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	96
				EQ-5D-3L Index Utility Score	1.000
			Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	96
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0138	SC	ES/SAF/FAS	Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	93
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	96
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	19
				EQ-5D-3L Index Utility Score	0.173
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	87
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0139	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	67
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	82
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	40
				EQ-5D-3L Index Utility Score	0.887
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	34
				EQ-5D-3L Index Utility Score	0.887
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	77
				EQ-5D-3L Index Utility Score	0.885
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	93
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0140	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	86
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	77
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	87
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	20
				EQ-5D-3L Index Utility Score	0.172
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.885
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	25
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	10
				EQ-5D-3L Index Utility Score	1.000
			Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0141	SC	ES/SAF/FAS	Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	39
				EQ-5D-3L Index Utility Score	0.697
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	92
				EQ-5D-3L Index Utility Score	0.887
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	0.887
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0142	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	88
				EQ-5D-3L Index Utility Score	0.886
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	48
				EQ-5D-3L Index Utility Score	0.786
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	87
				EQ-5D-3L Index Utility Score	0.886
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	86
				EQ-5D-3L Index Utility Score	0.887
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	76
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	83
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0143	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	87
				EQ-5D-3L Index Utility Score	0.887
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	86
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.698
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	92
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0144	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.786
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	35
				EQ-5D-3L Index Utility Score	0.886
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	15
				EQ-5D-3L Index Utility Score	0.887
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	9
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0145	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	96
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	40
				EQ-5D-3L Index Utility Score	0.787
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	40
				EQ-5D-3L Index Utility Score	0.785
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	0.999
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	0.886
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	49
				EQ-5D-3L Index Utility Score	0.886
			Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	59
				EQ-5D-3L Index Utility Score	0.885

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0146	SC	ES/SAF/FAS	Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	31
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	67
				EQ-5D-3L Index Utility Score	0.885
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	68
				EQ-5D-3L Index Utility Score	0.885
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	59
				EQ-5D-3L Index Utility Score	0.886

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	48
				EQ-5D-3L Index Utility Score	0.786
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0147	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	0.261
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.887
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.887
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	86
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0148	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.886
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	39
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	82
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	1.000
			Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	31
				EQ-5D-3L Index Utility Score	0.697
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	91
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0149	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	88
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.786

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0150	ES	Baseline	(Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	59
				EQ-5D-3L Index Utility Score	0.786

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	24
				EQ-5D-3L Index Utility Score	0.173
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0151	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.786
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	0.886
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	4
				EQ-5D-3L Index Utility Score	0.887
			Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0152	SC	ES/SAF/FAS	Visit 8	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	4
				EQ-5D-3L Index Utility Score	0.787
			Visit 9	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.787
			Visit 10	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	69
				EQ-5D-3L Index Utility Score	0.786
			Visit 11	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	78
				EQ-5D-3L Index Utility Score	0.786

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.463
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	0.999
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	50
				EQ-5D-3L Index Utility Score	0.785
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	93
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	29
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
01-0153	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	0.887
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	87
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	74
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	50
				EQ-5D-3L Index Utility Score	0.785
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	10
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	1
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	96
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0201	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	88
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	0
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0202	NDisc basic ES/SAF		Baseline (Visit 2a)	Mobility	I am confined to bed
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	0
				EQ-5D-3L Index Utility Score	-0.701
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	68.5
				EQ-5D-3L Index Utility Score	0.376
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.999
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	69
				EQ-5D-3L Index Utility Score	0.886
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.886
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	81
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0203	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.886
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	65
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	61
				EQ-5D-3L Index Utility Score	0.785
			Visit 10	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	55
				EQ-5D-3L Index Utility Score	0.785
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0204	NDisc basic	ES/SAF	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	74
				EQ-5D-3L Index Utility Score	0.785

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	25
				EQ-5D-3L Index Utility Score	-0.149
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	92
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0205	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.886
			Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	50
				EQ-5D-3L Index Utility Score	0.785
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.999
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.785
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.998

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0206	NDisc plus	ES/SAF/FAS	Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	87
				EQ-5D-3L Index Utility Score	0.887
			Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	87
				EQ-5D-3L Index Utility Score	0.999
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	0.999
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0207	ES	Baseline	(Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	40
				EQ-5D-3L Index Utility Score	0.260

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.886
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.785
			Visit 5	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.785
			Visit 6	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	69
				EQ-5D-3L Index Utility Score	0.786

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0208	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	71
				EQ-5D-3L Index Utility Score	0.786
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	50
				EQ-5D-3L Index Utility Score	0.786
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.886
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.887
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.999
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0209	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0210	ES	Baseline	(Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	25
				EQ-5D-3L Index Utility Score	0.172

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0211	NDisc basic ES/SAF		Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	0.785
			Visit 3a	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.785

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	81
				EQ-5D-3L Index Utility Score	0.786
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.786
			Visit 5	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.787
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887
			Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0212	SC	ES/SAF/FAS	Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.886
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0213	NDisc plus	ES/SAF	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	55
				EQ-5D-3L Index Utility Score	0.563

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	1.000
			Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am extremely anxious or depressed
				EQ VAS	40
				EQ-5D-3L Index Utility Score	0.398
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.885
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	55
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0214	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	52
				EQ-5D-3L Index Utility Score	0.885

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0215	ES	Baseline	(Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	55
				EQ-5D-3L Index Utility Score	0.261

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0216	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	40
				EQ-5D-3L Index Utility Score	0.376
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.887
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I am confined to bed
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	10
				EQ-5D-3L Index Utility Score	-0.702
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	74
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000
			Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0217	SC	ES/SAF/FAS	Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	74
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0218	NDisc basic	ES/SAF	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.786

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	40
				EQ-5D-3L Index Utility Score	0.172
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.885
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	50
				EQ-5D-3L Index Utility Score	0.886
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.885
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.886

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0219	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	65
				EQ-5D-3L Index Utility Score	0.886
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	64
				EQ-5D-3L Index Utility Score	0.886
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	67
				EQ-5D-3L Index Utility Score	0.999
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	74
				EQ-5D-3L Index Utility Score	0.999

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	40
				EQ-5D-3L Index Utility Score	0.785
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.886
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	69
				EQ-5D-3L Index Utility Score	0.886
			Visit 6	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	69
				EQ-5D-3L Index Utility Score	0.785
			Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	63
				EQ-5D-3L Index Utility Score	0.886

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0220	SC	ES/SAF/FAS	Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	71
				EQ-5D-3L Index Utility Score	0.886
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	63
				EQ-5D-3L Index Utility Score	0.885
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	61
				EQ-5D-3L Index Utility Score	0.886
			Visit 11	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	65
				EQ-5D-3L Index Utility Score	0.786

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0221	NDisc plus	ES/SAF	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	39
				EQ-5D-3L Index Utility Score	-0.149

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0222	NDisc plus	ES/SAF	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	-0.149

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	10
				EQ-5D-3L Index Utility Score	0.785
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	21
				EQ-5D-3L Index Utility Score	0.885
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	0.886
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.999
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.886

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0223	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.886
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am extremely anxious or depressed
				EQ VAS	89
			Visit 10	EQ-5D-3L Index Utility Score	0.612
				Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
			Visit 11	EQ VAS	79
				EQ-5D-3L Index Utility Score	0.999
				Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	92
				EQ-5D-3L Index Utility Score	0.999

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
02-0224	NDisc plus	ES/SAF	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	29
				EQ-5D-3L Index Utility Score	-0.150

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Baseline (Visit 2a)	Mobility	I am confined to bed
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	-0.702
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.885
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
04-0401	SC	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	65
				EQ-5D-3L Index Utility Score	0.886
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.886
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.999
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0602	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	72
				EQ-5D-3L Index Utility Score	0.999
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0604	NDisc basic	ES/SAF	Baseline (Visit 2a)	Mobility	I am confined to bed
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	40
				EQ-5D-3L Index Utility Score	-0.379

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0605	NDisc plus	ES/SAF	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	74
				EQ-5D-3L Index Utility Score	0.785

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	20
				EQ-5D-3L Index Utility Score	0.885
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	0.885
			Visit 5	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	25
				EQ-5D-3L Index Utility Score	0.172
			Visit 6	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	22
				EQ-5D-3L Index Utility Score	0.785
			Visit 7	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am extremely anxious or depressed
				EQ VAS	25
				EQ-5D-3L Index Utility Score	-0.449

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0606	SC	ES/SAF/FAS	Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am extremely anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	0.498
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	20
				EQ-5D-3L Index Utility Score	0.360
			Visit 10	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	22
				EQ-5D-3L Index Utility Score	0.260
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	0.885

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.887
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.887
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.787
			Visit 5	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	65
				EQ-5D-3L Index Utility Score	0.787
			Visit 6	Mobility	I have some problems in walking about
				Self-Care	I am unable to wash or dress myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	-0.033

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0607	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.786
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	69
				EQ-5D-3L Index Utility Score	0.886
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0608	SC	ES/SAF	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.697

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0609	NDisc basic	ES/SAF	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	40
				EQ-5D-3L Index Utility Score	0.885

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	50
				EQ-5D-3L Index Utility Score	0.785
			Visit 3a	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.785
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	87
				EQ-5D-3L Index Utility Score	0.999
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.885
			Visit 6	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.898

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0610	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	83
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	92
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0611	ES	Baseline	(Visit 2a)	Mobility	I am confined to bed
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	10
				EQ-5D-3L Index Utility Score	-0.701

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	25
				EQ-5D-3L Index Utility Score	0.887
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.887
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.887
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	91
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0612	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	92
				EQ-5D-3L Index Utility Score	0.887
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	92
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	68
				EQ-5D-3L Index Utility Score	
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	14
				EQ-5D-3L Index Utility Score	0.887
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.886

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0613	SC	ES/SAF/FAS	Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	25
				EQ-5D-3L Index Utility Score	-0.149
			Visit 3a	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	56
				EQ-5D-3L Index Utility Score	0.785
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.999
			Visit 5	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	25
				EQ-5D-3L Index Utility Score	0.785
			Visit 6	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	74
				EQ-5D-3L Index Utility Score	0.785

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0614	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	61
				EQ-5D-3L Index Utility Score	0.786
			Visit 8	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	49
				EQ-5D-3L Index Utility Score	0.785
			Visit 9	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	51
				EQ-5D-3L Index Utility Score	0.786
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.886
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0615	NDisc basic	ES/SAF	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	35
				EQ-5D-3L Index Utility Score	0.697

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0616	ES	Baseline	(Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	55
				EQ-5D-3L Index Utility Score	0.376

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0617	NDisc plus	ES/SAF	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	0.173
			Visit 3a	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	55
				EQ-5D-3L Index Utility Score	0.697

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0618	ES	Baseline	(Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.886

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	49
				EQ-5D-3L Index Utility Score	0.786
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	69
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	68
				EQ-5D-3L Index Utility Score	0.886
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	69
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0619	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.886
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am extremely anxious or depressed
				EQ VAS	19
				EQ-5D-3L Index Utility Score	0.176
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am extremely anxious or depressed
				EQ VAS	44
				EQ-5D-3L Index Utility Score	0.410
			Visit 10	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am extremely anxious or depressed
				EQ VAS	19
				EQ-5D-3L Index Utility Score	-0.215
			Visit 11	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am extremely anxious or depressed
				EQ VAS	21
				EQ-5D-3L Index Utility Score	0.310

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	45
				EQ-5D-3L Index Utility Score	0.885
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.886
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	74
				EQ-5D-3L Index Utility Score	0.886
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	82
				EQ-5D-3L Index Utility Score	0.887
			Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
06-0620	SC	ES/SAF/FAS	Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	78
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	65
				EQ-5D-3L Index Utility Score	0.886
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	72
				EQ-5D-3L Index Utility Score	0.886
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	1.000
			Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.261
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0701	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	87
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	86
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I am confined to bed
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am extremely anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	-1.089
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.375
			Visit 5	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.697
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.886
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	69
				EQ-5D-3L Index Utility Score	0.563

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0702	SC	ES/SAF/FAS	Visit 10	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.785

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.376
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	88
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	93
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0703	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	92
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	88
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	0.786
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0704	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	81
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0705	ES	Baseline	(Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	40
				EQ-5D-3L Index Utility Score	-0.150

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0706	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	0.697
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	29
				EQ-5D-3L Index Utility Score	0.785

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
07-0707	ES	Baseline	(Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.172

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0801	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	20
				EQ-5D-3L Index Utility Score	0.260
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.785
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.885
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	68
				EQ-5D-3L Index Utility Score	0.885

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	55
				EQ-5D-3L Index Utility Score	0.886
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	93
				EQ-5D-3L Index Utility Score	0.887
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0802	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	69
				EQ-5D-3L Index Utility Score	0.886
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0803	NDisc basic	ES/SAF/FAS	Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	74
				EQ-5D-3L Index Utility Score	1.000
			Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	55
				EQ-5D-3L Index Utility Score	0.786
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.887
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	96
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	96
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0804	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	100
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	45
				EQ-5D-3L Index Utility Score	0.885
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	0.886
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	68
				EQ-5D-3L Index Utility Score	0.886
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	77
				EQ-5D-3L Index Utility Score	0.999
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0805	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	83
				EQ-5D-3L Index Utility Score	0.886
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.886
			Visit 9	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	58
				EQ-5D-3L Index Utility Score	0.785
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	82
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.785
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.999
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	0.999
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	0.886
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	88
				EQ-5D-3L Index Utility Score	0.999

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0806	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.999
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am extremely anxious or depressed
				EQ VAS	71
				EQ-5D-3L Index Utility Score	0.612
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am extremely anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.499
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	93
				EQ-5D-3L Index Utility Score	0.886
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am extremely anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	0.499

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	29
				EQ-5D-3L Index Utility Score	0.260
			Visit 3a	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	49
				EQ-5D-3L Index Utility Score	0.785
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	59
				EQ-5D-3L Index Utility Score	0.886
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	0.886

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0807	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	0.886
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	49
				EQ-5D-3L Index Utility Score	0.886

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.786
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.886
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
08-0808	SC	ES/SAF/FAS	Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.886
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	71
				EQ-5D-3L Index Utility Score	0.886
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	86
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887
			Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0901	SC	ES/SAF/FAS	Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0903	NDisc plus	ES/SAF	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	0.785
			Visit 3a	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	65
				EQ-5D-3L Index Utility Score	0.785

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	49
				EQ-5D-3L Index Utility Score	0.173
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.885
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.885
			Visit 5	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	64
				EQ-5D-3L Index Utility Score	0.786
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	69
				EQ-5D-3L Index Utility Score	0.885

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0904	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	69
				EQ-5D-3L Index Utility Score	0.886
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.886
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.885
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.886
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	68
				EQ-5D-3L Index Utility Score	0.886

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.173
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.886
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.785
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	87
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0905	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	0.887
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	91
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	92
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	74
				EQ-5D-3L Index Utility Score	0.886
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0906	ES	Baseline	(Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	50
				EQ-5D-3L Index Utility Score	0.786

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.786
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	81
				EQ-5D-3L Index Utility Score	0.900
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	91
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	93
				EQ-5D-3L Index Utility Score	1.000
			Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0907	SC	ES/SAF/FAS	Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	58
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.261
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0908	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	96
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I am confined to bed
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	-0.701
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.999
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	88
				EQ-5D-3L Index Utility Score	0.887
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	99
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0909	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	96
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	96
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0910	NDisc plus	ES/SAF	Baseline (Visit 2a)	Mobility	I am confined to bed
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	9
				EQ-5D-3L Index Utility Score	-0.702

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	0.785
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	69
				EQ-5D-3L Index Utility Score	0.885
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	78
				EQ-5D-3L Index Utility Score	0.886
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0911	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	93
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	25
				EQ-5D-3L Index Utility Score	-0.061
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0912	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	96
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.886
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	0.885
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	92
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.999
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0913	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.886
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	93
				EQ-5D-3L Index Utility Score	0.999
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	0.999
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	91
				EQ-5D-3L Index Utility Score	0.999

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	0.173
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	69
				EQ-5D-3L Index Utility Score	0.798
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.887
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.887
			Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	0.999

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0914	SC	ES/SAF/FAS	Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	74
				EQ-5D-3L Index Utility Score	0.799
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	69
				EQ-5D-3L Index Utility Score	0.886
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	73
				EQ-5D-3L Index Utility Score	0.886

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	26
				EQ-5D-3L Index Utility Score	0.361
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	98
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0915	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	94
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	0.887
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	88
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	5
				EQ-5D-3L Index Utility Score	-0.149
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.786
			Visit 5	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	68
				EQ-5D-3L Index Utility Score	0.786
			Visit 6	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.786
			Visit 7	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.786

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
09-0916	SC	ES/SAF/FAS	Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.886
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	74
				EQ-5D-3L Index Utility Score	0.887
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	74
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
10-1001	ES	Baseline	(Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am extremely anxious or depressed
				EQ VAS	31
				EQ-5D-3L Index Utility Score	-0.537

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	40
				EQ-5D-3L Index Utility Score	0.375
			Visit 3a	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	0.786
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.886
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	93
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.786

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1101	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.786
			Visit 8	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	49
				EQ-5D-3L Index Utility Score	0.697
			Visit 9	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	39
				EQ-5D-3L Index Utility Score	0.786
			Visit 10	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	0.697
			Visit 11	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	29
				EQ-5D-3L Index Utility Score	0.697

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I am confined to bed
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	48
				EQ-5D-3L Index Utility Score	-0.702
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	73
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	73
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	77
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1102	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	88
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	83
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	91
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	77
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	82
				EQ-5D-3L Index Utility Score	0.999

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	25
				EQ-5D-3L Index Utility Score	-0.150
			Visit 4	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	24
				EQ-5D-3L Index Utility Score	0.785
			Visit 5	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.785
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	10
				EQ-5D-3L Index Utility Score	0.998
			Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	0.886

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1103	SC	ES/SAF/FAS	Visit 8	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	55
				EQ-5D-3L Index Utility Score	0.786
			Visit 9	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	50
				EQ-5D-3L Index Utility Score	0.260
			Visit 10	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	43
				EQ-5D-3L Index Utility Score	0.260
			Visit 11	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	39
				EQ-5D-3L Index Utility Score	0.785

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	76
				EQ-5D-3L Index Utility Score	0.787
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	77
				EQ-5D-3L Index Utility Score	1.000
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	82
				EQ-5D-3L Index Utility Score	1.000
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	86
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
11-1104	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	81
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	81
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	87
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	22
				EQ-5D-3L Index Utility Score	0.173
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.886
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	65
				EQ-5D-3L Index Utility Score	0.361
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.886
			Visit 6	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	-0.150

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
12-1201	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am extremely anxious or depressed
				EQ VAS	20
				EQ-5D-3L Index Utility Score	0.498
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	54
				EQ-5D-3L Index Utility Score	0.885
			Visit 9	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am extremely anxious or depressed
				EQ VAS	20
				EQ-5D-3L Index Utility Score	-0.127
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	34
				EQ-5D-3L Index Utility Score	0.360
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	40
				EQ-5D-3L Index Utility Score	0.886

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.376
			Visit 3a	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.786
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	77
				EQ-5D-3L Index Utility Score	0.886
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.886
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1301	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.887
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	0.886
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.886
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	83
				EQ-5D-3L Index Utility Score	0.887
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I am confined to bed
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	30
				EQ-5D-3L Index Utility Score	-0.702
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.886
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.887
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	87
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1302	NDisc plus	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	92
				EQ-5D-3L Index Utility Score	1.000
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	85
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	84
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	50
				EQ-5D-3L Index Utility Score	0.698
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	0.999
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	97
				EQ-5D-3L Index Utility Score	1.000
			Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1303	SC	ES/SAF/FAS	Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	95
				EQ-5D-3L Index Utility Score	1.000
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	92
				EQ-5D-3L Index Utility Score	1.000
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	69
				EQ-5D-3L Index Utility Score	0.887

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have some problems washing or dressing myself
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	20
				EQ-5D-3L Index Utility Score	0.172
			Visit 3a	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have some problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	60
				EQ-5D-3L Index Utility Score	0.885
			Visit 4	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.886
			Visit 5	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.999
			Visit 6	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	80
				EQ-5D-3L Index Utility Score	0.999

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1304	NDisc basic	ES/SAF/FAS	Visit 7	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have moderate pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	70
				EQ-5D-3L Index Utility Score	0.886
			Visit 8	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am extremely anxious or depressed
				EQ VAS	79
				EQ-5D-3L Index Utility Score	0.612
			Visit 9	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am moderately anxious or depressed
				EQ VAS	75
				EQ-5D-3L Index Utility Score	0.999
			Visit 10	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	90
				EQ-5D-3L Index Utility Score	1.000
			Visit 11	Mobility	I have no problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I have no problems with performing my usual activities
				Pain/Discomfort	I have no pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	89
				EQ-5D-3L Index Utility Score	1.000

Listing 16.2.2.6: EQ-5D-3L Questionnaire - all enrolled subjects

Site/Subject ID	Treatment Group	Analysis Set	Visit	Parameter	Answer
13-1305	NDisc plus	ES/SAF	Baseline (Visit 2a)	Mobility	I have some problems in walking about
				Self-Care	I have no problems with self-care
				Usual Activities	I am unable to perform my usual activities
				Pain/Discomfort	I have extreme pain or discomfort
				Anxiety/Depression	I am not anxious or depressed
				EQ VAS	20
				EQ-5D-3L Index Utility Score	-0.061

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 18OCT2012

Date of implantation : 15JAN2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Ligament sprain (Injury, poisoning and procedural complications)	04DEC2012		No	Moderate	Not recovered/ Not resolved	Not related	Not related	None	47,	-
Hypertension (Vascular disorders)	25DEC2012		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	68,	-
Spinal pain (Musculoskeletal and connective tissue disorders)	04FEB2013		No	Mild	Not recovered/ Not resolved	Related	Related	Specific drug treatment	109,	-
Cervicobrachial syndr ome (Nervous system disorders)	20FEB2013		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	125,	-
Osteoarthritis (Musculoskeletal and connective tissue disorders)	--FEB2013		No	Moderate	Not recovered/ Not resolved	Not related	Not related	None	133,	-
Rotator cuff syndrome (Musculoskeletal and connective tissue disorders)	25MAR2013	10OCT2013	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	158,	357
Rotator cuff syndrome (Musculoskeletal and connective tissue disorders)	10OCT2013	14OCT2013	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: arthroscopy	357,	361

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 18OCT2012

Date of implantation : 15JAN2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Subcutaneous abscess (Infections and infestations)	30OCT2013	03NOV2013	No	Moderate	Resolved, no sequalae	Not related	Not related	None	377, 381
Prostate cancer (Neoplasms benign, malignant and unspecified (incl cysts and polyps))	17DEC2013	03FEB2014	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: Prostatectomy	425, 473
Osteoarthritis (Musculoskeletal and connective tissue disorders)	30SEP2014	02OCT2014	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: ARTHROSCOPIC LAT. CLAVICULARESECTION	712, 714
Contusion (Injury, poisoning and procedural complications)	03DEC2016	23DEC2016	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1507, 1527

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 24OCT2012

Date of implantation : 22JAN2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Thermal burn (Injury, poisoning and procedural complications)	10DEC2012	25DEC2012	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	47,	62
Lymphangitis (Infections and infestations)	15DEC2012	25DEC2012	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	52,	62
Back pain (Musculoskeletal and connective tissue disorders)	25MAY2013	31DEC2013	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	213,	433
Intervertebral disc p rotrusion reported as herniated disc LWK 4 /5 (Musculoskeletal and connective tissue disorders)	31JUL2013	--DEC2013	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Other measures taken: Physiotherapy	280,	-
Headache (Nervous system disorders)	25DEC2013	25DEC2013	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	427,	427
Headache (Nervous system disorders)	02JAN2014	02JAN2014	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	435,	435
Bacterial infection (Infections and infestations)	14DEC2014	19DEC2014	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	781,	786

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 24OCT2012

Date of implantation : 22JAN2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Bacterial infection (Infections and infestations)	12JAN2015	17JAN2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	810,	815
Nasopharyngitis (Infections and infestations)	--OCT2017	--OCT2017	No	Mild	Resolved, no sequalae	Not related	Not related	None	1833,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 28NOV2012

Date of implantation : 19FEB2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Meniscus injury (Injury, poisoning and procedural complications)	31JAN2013	14FEB2013	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: arthroscopic partial meniscus resection	64,	78
Nasopharyngitis (Infections and infestations)	01APR2013	02APR2013	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	124,	125
Nasopharyngitis (Infections and infestations)	15JAN2014	22JAN2014	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	413,	420
Facet joint syndrome (Musculoskeletal and connective tissue disorders)	30DEC2014	06JAN2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	762,	769
Headache (Nervous system disorders)	01APR2015		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	854,	-
Parkinson's disease (Nervous system disorders)	03MAY2016	05MAY2016	Yes	Mild	Resolved with sequelae: Parkinson	Not related	Not related	Specific drug treatment	1252,	1254
Depression (Psychiatric disorders)	03MAY2016		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	1252,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 28NOV2012

Date of implantation : 19FEB2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Parkinson's disease (Nervous system disorders)	06MAY2016		No	Mild	Recovering/ Resolving	Not related	Not related	Specific drug treatment	1255, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 09JAN2013

Date of implantation : 09APR2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Headache (Nervous system disorders)	14JAN2013	15JAN2013	No	Mild	Resolved, no sequelae	Not related	Not related	Specific drug treatment	5,	6
Nausea (Gastrointestinal disorders)	14JAN2013	15JAN2013	No	Mild	Resolved, no sequelae	Not related	Not related	Specific drug treatment	5,	6
Gynaecomastia (Reproductive system and breast disorders)	03FEB2013	07FEB2013	Yes	Mild	Resolved, no sequelae	Not related	Not related	Subsequent surgical procedure: Gynaecomasty Re-surgery	25,	29
Hypercholesterolaemia (Metabolism and nutrition disorders)	08MAR2013		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	58,	-
Insomnia (Psychiatric disorders)	15APR2013		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	96,	-
Vertebral foraminal stenosis (Musculoskeletal and connective tissue disorders)	--SEP2017	--DEC2017	No	Mild	Resolved, no sequelae	Not related	Not related	Other measures taken: periradicular infiltration C5/C6	1725,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 10JAN2013

Date of implantation : 16APR2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Tooth extraction (Surgical and medical procedures)	28NOV2013	28NOV2013	No	Mild	Resolved, no sequalee	Not related	Not related	None	322, 322
Nasopharyngitis (Infections and infestations)	01JAN2018	07JAN2018	No	Mild	Resolved, no sequalee	Not related	Not related	Specific drug treatment	1817, 1823

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 24JAN2013

Date of implantation : 23APR2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Pulpitis dental (Infections and infestations)	07SEP2013	06OCT2013	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	226, 255
Haemorrhoids (Gastrointestinal disorders)	07NOV2013	28MAR2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	287, 1889
Eczema (Skin and subcutaneous tissue disorders)	07NOV2013	28MAR2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	287, 1889
Oropharyngeal pain (Respiratory, thoracic and mediastinal disorders)	31MAR2014	02APR2014	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	431, 433
Gastritis (Gastrointestinal disorders)	28NOV2014	28MAR2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	673, 1889
Diarrhoea (Gastrointestinal disorders)	20DEC2014	22DEC2014	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	695, 697
Hypercholesterolaemia (Metabolism and nutrition disorders)	05APR2017		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	1532, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 24JAN2013

Date of implantation : 23APR2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Back pain (Musculoskeletal and connective tissue disorders)	--NOV2017		No	Mild		Not related	Not related	Specific drug treatment	1771, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 12MAR2013

Date of implantation : 11JUN2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Erythema (Skin and subcutaneous tissue disorders)	20MAR2015	22MAR2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	738, 740
Pharyngitis (Infections and infestations)	15AUG2015	20AUG2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	886, 891
Tendon injury (Injury, poisoning and procedural complications)	23APR2017	08MAY2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1503, 1518
Skin laceration (Injury, poisoning and procedural complications)	21JAN2018	02FEB2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1776, 1788
Nasopharyngitis (Infections and infestations)	28MAY2018		No	Mild	Recovering/ Resolving	Not related	Not related	None	1903, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0112 Age=26 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 26MAR2013

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Intervertebral disc protrusion reported as recurrent herniation of lumbal discus (Musculoskeletal and connective tissue disorders)	02APR2013	07APR2013	Yes	Severe	Resolved, no sequelae	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: microscopic Sequesterectomy + Renucleotomy	7, 12

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 23MAY2013

Date of implantation : 06AUG2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Diarrhoea (Gastrointestinal disorders)	26MAY2013	27MAY2013	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	3,	4
Radiculopathy (Nervous system disorders)	11JUL2014	04AUG2014	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	414,	438
Intervertebral disc protrusion reported as REHERNIATION (Musculoskeletal and connective tissue disorders)	04AUG2014	09AUG2014	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: SEQUESTRECTOMY	438,	443
Intervertebral discitis (Infections and infestations)	02OCT2014	15OCT2014	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: SPONDYLODESIS	497,	510

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 11JUN2013

Date of implantation : 11SEP2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Sciatica (Nervous system disorders)	07AUG2013	23AUG2013	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	57,	73
Back pain (Musculoskeletal and connective tissue disorders)	24JUN2014	27JUN2014	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	378,	381
Goitre (Endocrine disorders)	21SEP2014	25SEP2014	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: Thyroidectomy	467,	471
Nasopharyngitis (Infections and infestations)	05FEB2015	15FEB2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	604,	614
Conjunctivitis (Infections and infestations)	--JUL2016	--JUL2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1146,	-
Nasopharyngitis (Infections and infestations)	--JAN2017	--JAN2017	No	Mild	Resolved, no sequalae	Not related	Not related	None	1330,	-
Contusion (Injury, poisoning and procedural complications)	14DEC2017	31DEC2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1647,	1664
Influenza (Infections and infestations)	--MAR2018	--MAR2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1754,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 12JUN2013

Date of implantation : 17SEP2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Endodontic procedure (Surgical and medical procedures)	24OCT2013	02NOV2013	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	134, 143
Hypertonia (Nervous system disorders)	11MAR2014		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	272, -
Diarrhoea (Gastrointestinal disorders)	17SEP2014	18SEP2014	No	Mild	Resolved, no sequalae	Not related	Not related	None	462, 463

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0116 Age=26 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 18JUN2013

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Seizure (Nervous system disorders)	18JUN2013 /14:00	18JUN2013	No	Mild	Resolved, no sequelae	Not related	Not related	None	0, 0

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 10JUL2013

Date of implantation : 08OCT2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Sciatica (Nervous system disorders)	15NOV2013		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	128,	-
Nasopharyngitis (Infections and infestations)	19NOV2013	23NOV2013	No	Mild	Resolved, no sequelae	Not related	Not related	Specific drug treatment	132,	136
Insomnia (Psychiatric disorders)	16FEB2014		No	Mild	Recovering/ Resolving	Not related	Not related	Specific drug treatment	221,	-
Intervertebral disc protrusion reported as REHERNIATION (Musculoskeletal and connective tissue disorders)	25MAR2014	07JUL2014	No	Moderate	Resolved, no sequelae	Not related	Not related	Specific drug treatment	258,	362
Intervertebral disc protrusion reported as reherniation (Musculoskeletal and connective tissue disorders)	08JUL2014	14JUL2014	Yes	Severe	Resolved, no sequelae	Not related	Not related	Subsequent surgical procedure: sequestrectomy	363,	369
Neuralgia (Nervous system disorders)	--JUL2014		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	386,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 10JUL2013

Date of implantation : 08OCT2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Intervertebral disc protrusion reported as disc prolaps L5/S1 left (Musculoskeletal and connective tissue disorders)	24MAY2016		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	1049,	-
Post laminectomy syndrome (Injury, poisoning and procedural complications)	16JAN2018	19JAN2018	Yes	Moderate	Resolved, no sequelae	Not related	Not related	Subsequent surgical procedure: Implantation of spinal cord stimulation	1651,	1654
Post laminectomy syndrome (Injury, poisoning and procedural complications)	01FEB2018	05FEB2018	Yes	Moderate	Resolved, no sequelae	Not related	Not related	Subsequent surgical procedure: Impulse generator implantation	1667,	1671

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 23JUL2013

Date of implantation : 15OCT2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Headache (Nervous system disorders)	15JAN2014	15JAN2014	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	176, 176
Headache (Nervous system disorders)	01MAR2014	01MAR2014	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	221, 221
Back pain (Musculoskeletal and connective tissue disorders)	14JUL2014	27JUL2014	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	356, 369
Osteoarthritis (Musculoskeletal and connective tissue disorders)	02MAR2015	04MAR2015	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: AC Joint resection	587, 589
Osteoarthritis (Musculoskeletal and connective tissue disorders)	27JUL2015	29JUL2015	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: AC Joint resection	734, 736
Nasopharyngitis (Infections and infestations)	--MAR2016	--MAR2016	No	Mild	Resolved, no sequalae	Not related	Not related	None	982, -
Back pain (Musculoskeletal and connective tissue disorders)	--JUL2016	--JUL2016	No	Mild	Resolved, no sequalae	Not related	Not related	None	1104, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 23JUL2013

Date of implantation : 15OCT2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Facet joint syndrome (Musculoskeletal and connective tissue disorders)	--AUG2017	28JUL2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1500, 1831	
Facet joint syndrome (Musculoskeletal and connective tissue disorders)	27JUL2018		Yes	Mild	Recovering/ Resolving	Not related	Not related	Subsequent surgical procedure: thermal denervation L3-5 right	1830,	-
Sciatica (Nervous system disorders)	03OCT2018		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	1898,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 15OCT2013

Date of implantation : 14JAN2014

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Nasopharyngitis (Infections and infestations)	29JAN2014	01FEB2014	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	106, 109
Nasopharyngitis (Infections and infestations)	01NOV2015	08NOV2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	747, 754

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 26SEP2013

Date of implantation : 17DEC2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Nasopharyngitis (Infections and infestations)	03MAR2014	09MAR2014	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	158, 164
Motion sickness (Ear and labyrinth disorders)	02OCT2014	12OCT2014	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	371, 381
Sinusitis (Infections and infestations)	27OCT2014	09NOV2014	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	396, 409
Ligament sprain (Injury, poisoning and procedural complications)	26AUG2015	07SEP2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	699, 711
Lumbar radiculopathy (Nervous system disorders)	11JUN2016	15JUN2016	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	989, 993
Bronchitis (Infections and infestations)	30MAR2017	12APR2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1281, 1294
Sinusitis (Infections and infestations)	30MAR2017	12APR2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1281, 1294
Motion sickness (Ear and labyrinth disorders)	27AUG2017	04SEP2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1431, 1439

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 26SEP2013

Date of implantation : 17DEC2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Chondritis (Musculoskeletal and connective tissue disorders)	06APR2018	14APR2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1653, 1661
Bronchitis (Infections and infestations)	16NOV2018	20NOV2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1877, 1881

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 16SEP2014

Date of implantation : 19DEC2014

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Back pain (Musculoskeletal and connective tissue disorders)	01JAN2015		No	Mild	Not recovered/ Not resolved	Not related	Not related	None	107,	-
Nasopharyngitis (Infections and infestations)	18FEB2015	02MAR2015	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	155,	167
Neuralgia (Nervous system disorders)	01MAR2015		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	166,	-
Intervertebral disc p rotrusion reported as DISC HERNIATION C6/7 left (Musculoskeletal and connective tissue disorders)	--NOV2016	05MAR2017	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	806,	901
Intervertebral disc p rotrusion reported as /12:22 DISCUS HERNIATION Hw k 6/7 (Musculoskeletal and connective tissue disorders)	06MAR2017	09MAR2017	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: Frykholm Hwk 6/7	902,	905
Radiculopathy (Nervous system disorders)	10MAR2017		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	906,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 16SEP2014

Date of implantation : 19DEC2014

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Nasopharyngitis (Infections and infestations)	--SEP2017	--SEP2017	No	Mild	Resolved, no sequaleae	Not related	Not related	None	1110, -
Intervertebral disc p rotrusion reported as Recidive discus hern iation L4/L5 right (Musculoskeletal and connective tissue disorders)	24MAY2018	29MAY2018	Yes	Moderate	Resolved, no sequaleae	Not related	Not related	Subsequent surgical procedure: sequestrectomy L3/L4 + L4/L5	1346, 1351
Intervertebral disc p rotrusion reported as discus herniation L3 /L4 (Musculoskeletal and connective tissue disorders)	24MAY2018	29MAY2018	Yes	Moderate	Resolved, no sequaleae	Not related	Not related	Subsequent surgical procedure: sequestrectomy L3/L4 + L4/L5	1346, 1351

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0124 Age=29 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 06NOV2014

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Fungal skin infection (Infections and infestations)	01OCT2014	30OCT2014	No	Mild	Resolved, no sequelae	Not related	Not related	Specific drug treatment	-36,	-8
Adjustment disorder w ith depressed mood (Psychiatric disorders)	06OCT2014		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	-31,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0125 Age=45 Sex=Male Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 07OCT2014

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Nasopharyngitis (Infections and infestations)	18FEB2015	20FEB2015	No	Mild	Resolved, no sequalae	Not related	Not related	None	134, 136
Back pain (Musculoskeletal and connective tissue disorders)	--FEB2017	--MAR2019	No	Mild	Resolved, no sequalae	Not related	Not related	None	875, -
Nasopharyngitis (Infections and infestations)	--MAR2017	--MAR2017	No	Mild	Resolved, no sequalae	Not related	Not related	None	906, -
Back pain (Musculoskeletal and connective tissue disorders)	22DEC2017	--MAR2019	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1172, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 08OCT2014

Date of implantation : 08JAN2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Cystitis (Infections and infestations)	07OCT2014	16OCT2014	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	-1,	8
Muscle spasms (Musculoskeletal and connective tissue disorders)	09OCT2014 /17:30	10OCT2014	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1,	2
Hypotension (Vascular disorders)	10OCT2014	10OCT2014	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	2,	2
Headache (Nervous system disorders)	07DEC2014	07DEC2014	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	60,	60
Headache (Nervous system disorders)	14JAN2015	14JAN2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	98,	98
Fall (Injury, poisoning and procedural complications)	16JAN2015	05FEB2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	100,	120
Sciatica (Nervous system disorders)	14FEB2015	04MAR2015	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	129,	147

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 08OCT2014

Date of implantation : 08JAN2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Intervertebral disc protrusion reported as Reherniation (Musculoskeletal and connective tissue disorders)	04MAR2015	13MAR2015	Yes	Moderate	Resolved, no sequelae	Not related	Not related	Subsequent surgical procedure: Sequestrectomy	147,	156
Abdominal pain (Gastrointestinal disorders)	12MAR2015	12MAR2015	No	Mild	Resolved, no sequelae	Not related	Not related	Specific drug treatment	155,	155
Erythema (Skin and subcutaneous tissue disorders)	06MAY2015	03JUN2015	No	Mild	Resolved, no sequelae	Not related	Not related	Specific drug treatment	210,	238
Flatulence (Gastrointestinal disorders)	09OCT2015	10OCT2015	No	Mild	Resolved, no sequelae	Not related	Not related	Specific drug treatment	366,	367
Nasopharyngitis (Infections and infestations)	--APR2017	--APR2017	No	Mild	Resolved, no sequelae	Not related	Not related	None	935,	-
Respiratory tract infection (Infections and infestations)	--APR2018	--APR2018	No	Mild	Resolved, no sequelae	Not related	Not related	Specific drug treatment	1300,	-
Syncope (Nervous system disorders)	--NOV2018	--NOV2018	No	Mild	Resolved, no sequelae	Not related	Not related	None	1514,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 08OCT2014

Date of implantation : 08JAN2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Back pain (Musculoskeletal and connective tissue disorders)	--MAY2019	--MAY2019	No	Mild	Resolved, no sequelae	Not related	Not related	Specific drug treatment	1696, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 20OCT2014

Date of implantation : 09JAN2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Seasonal allergy (Immune system disorders)	01MAY2015	30JUN2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	193, 253
Radiculopathy (Nervous system disorders)	27JUL2016	09OCT2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	646, 720
Sacral radiculopathy (Nervous system disorders)	--JUN2017		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	984, -
Arthralgia (Musculoskeletal and connective tissue disorders)	--JUL2017		No	Mild	Not recovered/ Not resolved	Not related	Not related	None	1015, -
Tooth extraction (Surgical and medical procedures)	04FEB2018	08FEB2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1203, 1207
Intervertebral disc p rotrusion reported as Reherniation/Discus prolaps L5/S1 right s ide (Musculoskeletal and connective tissue disorders)	14FEB2018	--MAR2018	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1213, -
Nasopharyngitis (Infections and infestations)	23FEB2018	25FEB2018	No	Mild	Resolved, no sequalae	Not related	Not related	None	1222, 1224

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 20OCT2014

Date of implantation : 09JAN2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Tooth infection (Infections and infestations)	09MAY2018	09MAY2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Other measures taken: root canal treatment	1297, 1297
Nasopharyngitis (Infections and infestations)	--JAN2019	--JAN2019	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1564, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 21OCT2014

Date of implantation : 13JAN2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Hypoaesthesia (Nervous system disorders)	-----2018		No	Mild	Recovering/ Resolving	Not related	Not related	Specific drug treatment	1532,	-
Sinusitis (Infections and infestations)	27OCT2014	18NOV2014	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	6,	28
Nasopharyngitis (Infections and infestations)	23NOV2015	30NOV2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	398,	405
Bacterial infection (Infections and infestations)	10JAN2018	24JAN2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1177,	1191
Back pain (Musculoskeletal and connective tissue disorders)	01MAR2019	--DEC2019	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1592,	-
Hypoaesthesia (Nervous system disorders)	01MAR2019	--DEC2019	No	Mild	Resolved, no sequalae	Not related	Not related	None	1592,	-
Nasopharyngitis (Infections and infestations)	--DEC2019	--DEC2019	No	Mild	Resolved, no sequalae	Not related	Not related	None	1897,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0129 Age=47 Sex=Male Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 29OCT2014

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Bacterial infection (Infections and infestations)	15OCT2015	17OCT2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	351, 353
Lumbar spinal stenosis (Musculoskeletal and connective tissue disorders)	23MAY2017	21JUL2017	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	937, 996
Vertebral foraminal stenosis (Musculoskeletal and connective tissue disorders)	15FEB2019	17MAR2019	No	Mild	Not recovered/ Not resolved	Not related	Not related	None	1570, 1600
Vertebral foraminal stenosis (Musculoskeletal and connective tissue disorders)	18MAR2019	23MAR2019	Yes	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: recessotomy L4/5 dext.	1601, 1606
Back pain (Musculoskeletal and connective tissue disorders)	--MAY2019	--JUN2019	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Other measures taken: Physiotherapy	1675, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 20NOV2014

Date of implantation : 03FEB2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Postmenopausal haemor rhage (Reproductive system and breast disorders)	--JAN2019	23APR2019	No	Mild	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: curretage + hysteroscopy	1533, 1615
Nasopharyngitis (Infections and infestations)	--FEB2019	--FEB2019	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1561, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 01DEC2014

Date of implantation : 19FEB2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Nasopharyngitis (Infections and infestations)	--OCT2018	--OCT2018	No	Mild	Resolved, no sequalae	Not related	Not related	None	1430,	-
Intervertebral disc p rotrusion reported as cervical disc protru sion C5/6 (Musculoskeletal and connective tissue disorders)	--NOV2018	--FEB2019	No	Mild	Resolved, no sequalae	Not related	Not related	Other measures taken: Physiotherapy	1460,	-
Headache (Nervous system disorders)	--JAN2019		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	1522,	-
Nasopharyngitis (Infections and infestations)	--SEP2019	--SEP2019	No	Mild	Resolved, no sequalae	Not related	Not related	None	1764,	-
Nasopharyngitis (Infections and infestations)	--DEC2019	--DEC2019	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1856,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0132 Age=25 Sex=Male Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 02DEC2014

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Haemorrhoids thrombosed (Gastrointestinal disorders)	08DEC2014	11DEC2014	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: MILLIGAN-MORGAN SURGERY	6,	9
Muscle tightness (Musculoskeletal and connective tissue disorders)	--MAY2017	--JAN2019	No	Mild	Resolved, no sequalae	Not related	Not related	Other measures taken: Physiotherapy, massage, cupping	911,	-
Sinusitis (Infections and infestations)	--JUN2017	--JUN2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	941,	-
Wisdom teeth removal (Surgical and medical procedures)	06DEC2018	12DEC2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: Osteotomy	1465,	1471
Back pain (Musculoskeletal and connective tissue disorders)	--SEP2019	--NOV2019	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1763,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0133 Age=52 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 16DEC2014

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Intervertebral disc p rotrusion reported as REHERNIATION (Musculoskeletal and connective tissue disorders)	29DEC2014	07JAN2015	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: SEQUESTRECTOMY + MICRODISCECTOMY	13, 22

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0134 Age=29 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 17DEC2014

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Bursitis (Musculoskeletal and connective tissue disorders)	10JAN2015	20JAN2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	24, 34

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 15JAN2015

Date of implantation : 08APR2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Pyrexia (General disorders and administration site conditions)	16JAN2015	21JAN2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1,	6
Nasopharyngitis (Infections and infestations)	20MAY2015	24MAY2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	125,	129
Back pain (Musculoskeletal and connective tissue disorders)	--DEC2017		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	1081,	-
Respiratory tract infection (Infections and infestations)	--JAN2019	--JAN2019	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1477,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 23FEB2015

Date of implantation : 02JUN2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Thrombosis (Vascular disorders)	07APR2015	23APR2015	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	43,	59
Lumbar radiculopathy (Nervous system disorders)	01JUL2015		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	128,	-
Intervertebral disc p rotrusion reported as Reherniation L4/L5 r ight (Musculoskeletal and connective tissue disorders)	21OCT2015		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	240,	-
Renal infarct (Renal and urinary disorders)	19FEB2016 /09:00	25FEB2016	Yes	Moderate	Resolved with sequelae: Thrombosis prophylaxis needed	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: ANGIOGRAPHY + THROMBECTOMY	361,	367
Hypoaesthesia (Nervous system disorders)	--FEB2016		No	Mild	Not recovered/ Not resolved	Not related	Not related	None	370,	-
Skin laceration (Injury, poisoning and procedural complications)	02AUG2017	03OCT2017	No	Mild	Resolved, no sequalae	Not related	Not related	Other measures taken: tendon + wound were stitched	891,	953

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 26FEB2015

Date of implantation : 02JUN2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Arthralgia (Musculoskeletal and connective tissue disorders)	-----2017		No	Mild	Not recovered/ Not resolved	Not related	Not related	None	1039,	-
Goitre (Endocrine disorders)	20JUN2016		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	480,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 09MAR2015

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Oropharyngeal pain (Respiratory, thoracic and mediastinal disorders)	10MAR2015	19MAR2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1, 10
Seasonal allergy (Immune system disorders)	15MAR2015	31MAR2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	6, 22
Nasopharyngitis (Infections and infestations)	09SEP2015	14SEP2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	184, 189
Nasopharyngitis (Infections and infestations)	27DEC2015	02JAN2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	293, 299
Seasonal allergy (Immune system disorders)	20FEB2016	22MAY2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	348, 805
Nasopharyngitis (Infections and infestations)	31DEC2016	04JAN2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	663, 667
Joint dislocation (Injury, poisoning and procedural complications)	20JAN2018	--SEP2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1048, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 09MAR2015

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Nasopharyngitis (Infections and infestations)	17FEB2018	21FEB2018	No	Mild	Resolved, no sequalae	Not related	Not related	None	1076, 1080
Gastroesophageal ref lux disease (Gastrointestinal disorders)	23JUL2018		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	1232, -
Seasonal allergy (Immune system disorders)	27FEB2019	16APR2019	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1451, 1499
Nasopharyngitis (Infections and infestations)	22DEC2019	26DEC2019	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1749, 1753
Hypertension (Vascular disorders)	03JAN2020	03JAN2020	No	Mild	Resolved, no sequalae	Not related	Not related	None	1761, 1761
Spinal cord neoplasm (Neoplasms benign, malignant and unspecified (incl cysts and polyps))	12FEB2020		No	Mild	Not recovered/ Not resolved	Not related	Not related	None	1801, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0139 Age=29 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 10MAR2015

Date of implantation : 03JUN2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Nausea (Gastrointestinal disorders)	10MAR2015 /17:30	10MAR2015	No	Mild	Resolved, no sequalee	Not related	Not related	Specific drug treatment	0,	0
Intervertebral disc protrusion reported as REHERNIATION L5/S1 RIGHT (Musculoskeletal and connective tissue disorders)	11DEC2016	22JAN2017	No	Moderate	Resolved, no sequalee	Not related	Not related	Specific drug treatment	642,	684
Intervertebral disc protrusion reported as Reherniation L5/S1 right (Musculoskeletal and connective tissue disorders)	23JAN2017	-----2017	Yes	Moderate	Resolved, no sequalee	Not related	Not related	Subsequent surgical procedure: Sequestrectomia	685,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 12MAY2015

Date of implantation : 11AUG2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Vertigo (Ear and labyrinth disorders)	15MAY2015	15OCT2015	No	Mild	Resolved, no sequalae	Not related	Not related	None	3, 156
Erythema (Skin and subcutaneous tissue disorders)	18MAY2015	23MAY2015	No	Mild	Resolved, no sequalae	Not related	Not related	None	6, 11
Endodontic procedure (Surgical and medical procedures)	22SEP2015	22SEP2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	133, 133
Nasopharyngitis (Infections and infestations)	--JUN2017	--JUN2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	780, -
Nasopharyngitis (Infections and infestations)	--DEC2017	--DEC2017	No	Mild	Resolved, no sequalae	Not related	Not related	None	964, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0141 Age=27 Sex=Female Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 27MAY2015

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Abortion spontaneous (Pregnancy, puerperium and perinatal conditions)	--SEP2016	--SEP2016	No	Mild	Resolved, no sequalae	Not related	Not related	None	492,	-
Abortion spontaneous (Pregnancy, puerperium and perinatal conditions)	--JAN2017	--JAN2017	No	Mild	Resolved, no sequalae	Not related	Not related	None	615,	-
Nasopharyngitis (Infections and infestations)	--JAN2017	--JAN2017	No	Mild	Resolved, no sequalae	Not related	Not related	None	615,	-
Sciatica (Nervous system disorders)	--APR2019	--APR2019	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1434,	-
Perineal injury (Injury, poisoning and procedural complications)	27SEP2020 /16:00	30SEP2020	No	Mild	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: suture	1950, 1953	
Ear operation (Surgical and medical procedures)	30OCT2020	30OCT2020	No	Mild	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: excision	1983, 1983	
Headache (Nervous system disorders)	--FEB2021	--FEB2021	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	2104,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 27MAY2015

Date of implantation : 25AUG2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Back pain (Musculoskeletal and connective tissue disorders)	-----2018		No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1314,	-
Nasopharyngitis (Infections and infestations)	--FEB2018	--FEB2018	No	Mild	Resolved, no sequalae	Not related	Not related	None	1008,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 17JUN2015

Date of implantation : 22SEP2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Oropharyngeal pain (Respiratory, thoracic and mediastinal disorders)	19JUN2015	19JUN2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	2,	2
Nasopharyngitis (Infections and infestations)	--MAR2018	--MAR2018	No	Mild	Resolved, no sequalae	Not related	Not related	None	1018,	-
Nasopharyngitis (Infections and infestations)	--JAN2019	--JAN2019	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1324,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 24JUN2015

Date of implantation : 22SEP2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Headache (Nervous system disorders)	21SEP2015 /16:00	21SEP2015 /20:00	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	89,	89
Pharyngitis (Infections and infestations)	--APR2018	--APR2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1041,	-
Intervertebral disc protrusion reported as disc reherniation L5/S1 (Musculoskeletal and connective tissue disorders)	--NOV2018	--MAY2019	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Other measures taken: NERVE ROOT INFILTRATION (05/19)	1255,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 16JUL2015

Date of implantation : 07OCT2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Arthralgia (Musculoskeletal and connective tissue disorders)	17JUL2015		No	Moderate	Recovering/ Resolving	Not related	Not related	Specific drug treatment	1,	-
Cystitis (Infections and infestations)	19JUL2015	21JUL2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	3,	5
Salpingitis (Infections and infestations)	17NOV2015	23NOV2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	124,	130
Neck pain (Musculoskeletal and connective tissue disorders)	20DEC2015		No	Mild	Recovering/ Resolving	Not related	Not related	Specific drug treatment	157,	-
Urinary tract infecti on (Infections and infestations)	--JUN2017	--JUN2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	715,	-
Herpes zoster (Infections and infestations)	--DEC2017	--DEC2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	899,	-
Herpes zoster (Infections and infestations)	19MAR2018	27MAR2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	977,	985

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 16JUL2015

Date of implantation : 07OCT2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Urinary tract infecti on (Infections and infestations)	03AUG2018	09AUG2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1114,	1120
Herpes zoster (Infections and infestations)	--SEP2019	--SEP2019	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1537,	-
Back pain (Musculoskeletal and connective tissue disorders)	15NOV2019	--DEC2019	No	Moderate	Resolved, no sequalae	Related	Not related	Specific drug treatment	1583,	-
Urinary tract infecti on (Infections and infestations)	29SEP2020	--OCT2020	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1902,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0146 Age=50 Sex=Male Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 16JUL2015

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Back pain (Musculoskeletal and connective tissue disorders)	--OCT2015		No	Mild	Recovering/ Resolving	Not related	Not related	Specific drug treatment	107,	-
Nasopharyngitis (Infections and infestations)	--APR2019	--APR2019	No	Mild	Resolved, no sequalae	Not related	Not related	None	1384,	-
Sleep apnoea syndrome (Respiratory, thoracic and mediastinal disorders)	01JAN2020		No	Mild	Not recovered/ Not resolved	Not related	Not related	Other measures taken: n CPAP	1630,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 20AUG2015

Date of implantation : 18NOV2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Nasopharyngitis (Infections and infestations)	22OCT2015	15NOV2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	63,	87
Nasopharyngitis (Infections and infestations)	23NOV2015	30NOV2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	95,	102
Arthralgia (Musculoskeletal and connective tissue disorders)	05SEP2016	12SEP2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	382,	389
Nasopharyngitis (Infections and infestations)	31OCT2016	07NOV2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	438,	445
Toothache (Gastrointestinal disorders)	17APR2017	28APR2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	606,	617
Urinary tract infecti on (Infections and infestations)	24MAY2017	26MAY2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	643,	645
Bronchitis (Infections and infestations)	06JUN2017	15JUN2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	656,	665
Nasopharyngitis (Infections and infestations)	12FEB2018	16FEB2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	907,	911

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 20AUG2015

Date of implantation : 18NOV2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Arthralgia (Musculoskeletal and connective tissue disorders)	--APR2020		No	Mild	Recovering/ Resolving	Not related	Not related	Other measures taken: osteopathy	1715, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 22OCT2015

Date of implantation : 12JAN2016

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Pulmonary mass (Respiratory, thoracic and mediastinal disorders)	12JAN2016 /09:00	18JAN2016	No	Mild	Resolved, no sequalae	Not related	Not related	None	82,	88
Helicobacter infectio n (Infections and infestations)	14JAN2016	09FEB2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	84,	110
Pulmonary mass (Respiratory, thoracic and mediastinal disorders)	19JAN2016	20JAN2016	Yes	Mild	Resolved, no sequalae	Not related	Not related	Other measures taken: BIOPSY	89,	90
Herpes zoster (Infections and infestations)	--MAY2017	--MAY2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	587,	-
Back pain (Musculoskeletal and connective tissue disorders)	--JUN2017		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	617,	-
Nasopharyngitis (Infections and infestations)	--OCT2018	--OCT2018	No	Mild	Resolved, no sequalae	Not related	Not related	None	1105,	-
Nasopharyngitis (Infections and infestations)	--JAN2019	--JAN2019	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1197,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 03DEC2015

Date of implantation : 01MAR2016

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Nasopharyngitis (Infections and infestations)	07JAN2016	15JAN2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	35,	43
Nasopharyngitis (Infections and infestations)	28JAN2016	02FEB2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	56,	61
Urinary tract infecti on (Infections and infestations)	--JAN2017	--FEB2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	425,	-
Lumbar radiculopathy (Nervous system disorders)	01NOV2017	08NOV2017	No	Mild	Resolved, no sequalae	Not related	Not related	None	699,	706
Bronchitis (Infections and infestations)	20FEB2018	--MAR2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	810,	-
Nasopharyngitis (Infections and infestations)	31DEC2018	08JAN2019	No	Mild	Resolved, no sequalae	Not related	Not related	None	1124,	1132
Back pain (Musculoskeletal and connective tissue disorders)	--DEC2018	--DEC2018	No	Mild	Resolved, no sequalae	Not related	Not related	None	1124,	-
Sciatica (Nervous system disorders)	--OCT2020		No	Mild	Not recovered/ Not resolved	Not related	Not related	None	1794,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 03DEC2015

Date of implantation : 01MAR2016

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Urinary tract infection (Infections and infestations)	--NOV2020	--NOV2020	No	Mild	Resolved, no sequelae	Not related	Not related	Specific drug treatment	1824, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 03MAR2016

Date of implantation : 07JUN2016

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Nasopharyngitis (Infections and infestations)	-----2018	-----2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1033,	-
Skin laceration (Injury, poisoning and procedural complications)	--JAN2019	--JAN2019	No	Mild	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: suture	1064,	-
Nasopharyngitis (Infections and infestations)	--DEC2019	--DEC2019	No	Mild	Resolved, no sequalae	Not related	Not related	None	1398,	-
Sinusitis (Infections and infestations)	--JAN2020	--JAN2020	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1429,	-
Nasopharyngitis (Infections and infestations)	--JAN2021	--JAN2021	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1795,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0152 Age=55 Sex=Female Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 03MAR2016

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Procedural vomiting (Injury, poisoning and procedural complications)	03MAR2016 /10:00	04MAR2016	No	Mild	Resolved, no sequalae	Related	Not related	Specific drug treatment	0,	1
Procedural nausea (Injury, poisoning and procedural complications)	03MAR2016 /10:00	04MAR2016	No	Mild	Resolved, no sequalae	Related	Not related	Specific drug treatment	0,	1
Procedural vomiting (Injury, poisoning and procedural complications)	03MAR2016 /10:00	04MAR2016	No	Mild	Resolved, no sequalae	Related	Not related	Specific drug treatment	0,	1
Back pain (Musculoskeletal and connective tissue disorders)	--FEB2018	--DEC2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	727,	-
Sciatica (Nervous system disorders)	--DEC2019	31JAN2020	No	Mild	Resolved with sequelae: Lumbago; no sensomot. deficit	Not related	Not related	Specific drug treatment	1398,	1429
Ear infection (Infections and infestations)	--DEC2020	--DEC2020	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1764,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 21MAR2016

Date of implantation : 07JUN2016

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Back pain (Musculoskeletal and connective tissue disorders)	15JUN2016	07JUN2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	86,	443
Type 1 diabetes melli tus (Metabolism and nutrition disorders)	26JAN2018	31JAN2018	Yes	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	676,	681
Type 1 diabetes melli tus (Metabolism and nutrition disorders)	01FEB2018		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	682,	-
Radicular pain (Nervous system disorders)	--NOV2018	--FEB2019	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Other measures taken: physiotherapy + massage	984,	-
Nasopharyngitis (Infections and infestations)	--DEC2018	--DEC2018	No	Mild	Resolved, no sequalae	Not related	Not related	None	1015,	-
Migraine (Nervous system disorders)	01MAY2019		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	1136,	-
Nasopharyngitis (Infections and infestations)	--OCT2019	--OCT2019	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1319,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 21MAR2016

Date of implantation : 07JUN2016

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Nasopharyngitis (Infections and infestations)	--DEC2019	--DEC2019	No	Mild	Resolved, no sequalae	Not related	Not related	None	1380,	-
Nasopharyngitis (Infections and infestations)	--JAN2020	--JAN2020	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1411,	-
Back pain (Musculoskeletal and connective tissue disorders)	--JUL2020		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment, Other measures taken: Physiotherapy	1593,	-
Appendicitis (Infections and infestations)	--JUL2020	--JUL2020	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: Appendectomy	1593,	-
Nasopharyngitis (Infections and infestations)	--APR2021	--APR2021	No	Mild	Resolved, no sequalae	Not related	Not related	None	1866,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 13FEB2013

Date of implantation : 07MAY2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Tendonitis (Musculoskeletal and connective tissue disorders)	--SEP2013	30OCT2013	No	Mild	Resolved, no sequalae	Not related	Not related	Other measures taken: MRI 23.10.2013 left ankle joint	229, 259
Ankle fracture (Injury, poisoning and procedural complications)	--SEP2013	30OCT2013	No	Mild	Resolved, no sequalae	Not related	Not related	Other measures taken: MRI 23.10.2013	229, 259
Intervertebral disc p rotrusion reported as Rezidiv prolaps L4/5 right side (Musculoskeletal and connective tissue disorders)	28DEC2015 /15:30	04JAN2016 /12:00	Yes	Moderate	Resolved, no sequalae	Related	Related	Specific drug treatment, Subsequent surgical procedure: Sequestrectomie L4 L5	1048, 1055

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=02/0202 Age=47 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 20MAR2013

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Pain in extremity (Musculoskeletal and connective tissue disorders)	22MAR2013 /19:08	25MAR2013	No	Mild	Resolved, no sequalae	Not related	NA	Other measures taken: D-Dimer Labor	2, 5

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 28MAR2013

Date of implantation : 26JUN2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Areflexia (Nervous system disorders)	13AUG2013		No	Mild	Recovering/ Resolving	Not related	Not related	None	138,	-
Arthralgia (Musculoskeletal and connective tissue disorders)	26FEB2014 /12:06	26FEB2014 /14:00	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	335,	335
Intervertebral disc protrusion reported as Disc herniation L3/L4 right (Musculoskeletal and connective tissue disorders)	05MAR2014 /10:30	10MAR2014 /07:00	No	Moderate	Resolved, no sequalae	Not related	Related	Specific drug treatment	342,	347
Back pain (Musculoskeletal and connective tissue disorders)	--FEB2016		No	Mild	Recovering/ Resolving	Not related	Not related	Specific drug treatment	1067,	-
Facet joint syndrome (Musculoskeletal and connective tissue disorders)	20JUL2016 /14:00	11AUG2016 /14:30	No	Mild	Resolved, no sequalae	Not related	Not related	None	1210,	1232

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 18APR2013

Date of implantation : 31JUL2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Asthma (Respiratory, thoracic and mediastinal disorders)	--AUG2015		No	Mild	Unknown	Not related	Not related	Specific drug treatment	865, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 01JUL2013

Date of implantation : 08OCT2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Respiration abnormal (Respiratory, thoracic and mediastinal disorders)	20AUG2013	--FEB2014	No	Mild	Resolved, no sequalae	Not related	Not related	None	50,	-
Gastric disorder (Gastrointestinal disorders)	20AUG2013	--FEB2014	No	Mild	Resolved, no sequalae	Not related	Not related	None	50,	-
Hypertension (Vascular disorders)	--AUG2013		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	61,	-
Contusion (Injury, poisoning and procedural complications)	31MAR2014	08APR2014	No	Mild	Resolved, no sequalae	Not related	Not related	Other measures taken: buddy tape - bandage	273,	281
Colitis ulcerative (Gastrointestinal disorders)	--AUG2015		Yes	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	791,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 12SEP2013

Date of implantation : 10DEC2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Intervertebral disc protrusion reported as Disc reherniation L5/S1 (Musculoskeletal and connective tissue disorders)	16DEC2013	19DEC2013	Yes	Moderate	Resolved, no sequelae	Related	Related	Specific drug treatment	95,	98
Ligament sprain (Injury, poisoning and procedural complications)	10MAR2014	01APR2014	No	Mild	Resolved, no sequelae	Not related	Not related	None	179,	201
Intervertebral disc protrusion reported as suspected Reizidivprolaps L5/S1 in MRI (Musculoskeletal and connective tissue disorders)	25MAR2014	31MAR2014	No	Moderate	Resolved, no sequelae	Related	Related	Specific drug treatment	194,	200
Intervertebral disc protrusion reported as Suspected Reizidivprolaps L5/S1 in MRI (Musculoskeletal and connective tissue disorders)	01APR2014 /08:15	08APR2014 /10:02	Yes	Moderate	Resolved, no sequelae	Related	Related	Subsequent surgical procedure: Sequestrectomy revision relapse on 02.04.2014	201,	208

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 12SEP2013

Date of implantation : 10DEC2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Intervertebral disc protrusion reported as Rezidiv L5/S1 Prolaps MRI 04.09.2015 (Musculoskeletal and connective tissue disorders)	01SEP2015	20SEP2015 /10:00	No	Moderate	Resolved, no sequelae	Related	Related	Other measures taken: MRI	719, 738
Intervertebral disc protrusion reported as Rezidiv prolaps L5/S1 left (Musculoskeletal and connective tissue disorders)	21SEP2015 /10:00	28SEP2015 /10:00	Yes	Moderate	Resolved, no sequelae	Related	Related	Subsequent surgical procedure: Sequestrectomy L5/S1 left	739, 746

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 23OCT2014

Date of implantation : 30JAN2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Pain in extremity (Musculoskeletal and connective tissue disorders)	03NOV2015	05NOV2015 /09:00	No	Mild	Resolved, no sequalae	Not related	Not related	None	376, 378

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=02/0211 Age=28 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 11DEC2014

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Intervertebral disc protrusion reported as Rezidiv L5/S1 (Musculoskeletal and connective tissue disorders)	04MAR2015	05MAR2015	No	Moderate	Resolved, no sequelae	Not related	Not related	Other measures taken: conservative therapy/physiotherapy	83, 84

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=02/0212 Age=36 Sex=Male Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 16DEC2014

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Staphylococcal infection (Infections and infestations)	11JAN2016	17JAN2016	No	Mild	Resolved, no sequelae	Not related	Not related	Specific drug treatment	391, 397
Back pain (Musculoskeletal and connective tissue disorders)	16APR2019 /13:00	30DEC2019	No	Mild	Resolved, no sequelae	Related	Not related	Other measures taken: physical therapy	1582, 1840

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=02/0214 Age=26 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 25FEB2015

Date of implantation : 28MAY2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Sciatica (Nervous system disorders)	--AUG2020	15OCT2020 /13:00	No	Moderate	Resolved, no sequalae	Not related	Related	None	2014, 2059
Intervertebral disc p rotrusion reported as Recurrent disc herni ation (Musculoskeletal and connective tissue disorders)	15OCT2020	16OCT2020	Yes	Moderate	Resolved, no sequalae	Not related	Related	Specific drug treatment	2059, 2060

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=02/0216 Age=37 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 28APR2015

Date of implantation : 23JUL2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Back pain (Musculoskeletal and connective tissue disorders)	07AUG2015	20AUG2015	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	101, 114
Intervertebral disc p rotrusion reported as Rezidiv intervertebr al disk L5/S1 right (Musculoskeletal and connective tissue disorders)	21AUG2015	29MAR2016	No	Moderate	Resolved, no sequalae	Related	Related	Specific drug treatment	115, 336

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=02/0217 Age=29 Sex=Male Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 28MAY2015

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Sciatica (Nervous system disorders)	--JAN2017	--JAN2017	No	Mild	Resolved, no sequelae	Not related	Not related	None	614, -
Respiratory tract infection (Infections and infestations)	14FEB2018	15FEB2018	No	Mild	Resolved, no sequelae	Not related	Not related	None	993, 994
Bacterial infection (Infections and infestations)	08MAR2018	09MAR2018	No	Mild	Resolved, no sequelae	Not related	Not related	None	1015, 1016
Back pain (Musculoskeletal and connective tissue disorders)	13MAR2018	01JUL2020	No	Moderate	Resolved, no sequelae	Related	Not related	None	1020, 1861
Subcutaneous abscess (Infections and infestations)	25APR2018	25APR2018	No	Mild	Resolved, no sequelae	Not related	Not related	None	1063, 1063
Lumbar radiculopathy (Nervous system disorders)	07DEC2018	14DEC2018	No	Mild	Resolved, no sequelae	Not related	Not related	None	1289, 1296

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 11JUN2015

Date of implantation : 25SEP2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Nasopharyngitis (Infections and infestations)	--JAN2019	--FEB2019	No	Mild	Resolved, no sequalee	Not related	Not related	None	1330, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=02/0220 Age=44 Sex=Female Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 13AUG2015

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Nasopharyngitis (Infections and infestations)	--APR2019	--APR2019	No	Mild	Resolved, no sequaleae	Not related	Not related	Specific drug treatment	1356,	-
Skin lesion (Skin and subcutaneous tissue disorders)	22JUN2020	--JUL2020	No	Mild	Resolved, no sequaleae	Not related	Not related	Other measures taken: Air-Go splint	1775,	-
Myelopathy (Nervous system disorders)	02SEP2020 /14:00		No	Mild	Not recovered/ Not resolved	Not related	Not related	None	1847,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=02/0221 Age=48 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 01SEP2015

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Intervertebral disc protrusion reported as Rezidiv L4/L5 left (Musculoskeletal and connective tissue disorders)	10DEC2015	10DEC2015	No	Mild	Resolved, no sequelae	Related	Not related	Other measures taken: IRENA Rehabilitation	100, 100

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 29DEC2015

Date of implantation : 22MAR2016

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Rhinitis allergic (Respiratory, thoracic and mediastinal disorders)	21MAR2016		No	Mild	Recovering/ Resolving	Not related	Not related	Specific drug treatment	83,	-
Arthralgia (Musculoskeletal and connective tissue disorders)	--MAY2016	03MAR2021	No	Mild	Recovering/ Resolving	Not related	Not related	Specific drug treatment	154,	1891
Spinal osteoarthritis (Musculoskeletal and connective tissue disorders)	15MAR2017 /14:00		No	Mild	Unknown	Not related	Not related	None	442,	-
Nerve block (Surgical and medical procedures)	15MAR2017 /14:00	03MAR2021	No	Mild	Unknown	Not related	Not related	None	442,	1891
Tendon calcification (Musculoskeletal and connective tissue disorders)	25JAN2018 /10:00	27JAN2018	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: Arthroscopy shoulder, outpatient treatment	758,	760
Osteoarthritis (Musculoskeletal and connective tissue disorders)	--FEB2019	26APR2019	No	Mild	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: Rhizotomy thumb	1157,	1214

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 29DEC2015

Date of implantation : 22MAR2016

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Osteoarthritis (Musculoskeletal and connective tissue disorders)	--APR2019		No	Mild	Not recovered/ Not resolved	Not related	Not related	Subsequent surgical procedure: Rhizotomie	1218, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 23JUL2013

Date of implantation : 05NOV2013

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Depression (Psychiatric disorders)	05JAN2015	31MAR2015	No	Moderate	Resolved, no sequelae	Not related	Not related	Specific drug treatment	531, 616

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=06/0605 Age=51 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 11DEC2014

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Dural tear (Injury, poisoning and procedural complications)	11DEC2014 /11:00	11DEC2014 /13:15	No	Mild	Resolved, no sequalae	Related	Not related	Subsequent surgical procedure: surgical suture	0, 0

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 16DEC2014

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Nausea (Gastrointestinal disorders)	18DEC2014	19DEC2014	No	Moderate	Resolved, no sequelae	Not related	Not related	Specific drug treatment	2,	3
Depression (Psychiatric disorders)	18DEC2014	07JUL2015	No	Mild	Resolved, no sequelae	Not related	Not related	Specific drug treatment	2,	203
Diabetes mellitus (Metabolism and nutrition disorders)	--JAN2015		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	46,	-
Back pain (Musculoskeletal and connective tissue disorders)	--JAN2015	--AUG2015	No	Mild	Resolved, no sequelae	Not related	Not related	Specific drug treatment	46,	-
Erythema (Skin and subcutaneous tissue disorders)	06FEB2015	--FEB2015	No	Mild	Resolved, no sequelae	Not related	Not related	None	52,	-
Sciatica (Nervous system disorders)	04MAR2015 /16:00	14MAR2015	No	Mild	Resolved with sequelae: remaining ischialgy	Related	Not related	None	78,	88
Sacroiliac joint dysf unction (Musculoskeletal and connective tissue disorders)	14MAR2015	25SEP2016	No	Moderate	Resolved, no sequelae	Not related	Not related	None	88,	649

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 16DEC2014

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Nausea (Gastrointestinal disorders)	23SEP2015		No	Mild	Not recovered/ Not resolved	Not related	Not related	Other measures taken: acupuncture	281,	-
Gastrointestinal hypo motility (Gastrointestinal disorders)	19OCT2015		No	Mild	Recovering/ Resolving	Not related	Not related	Specific drug treatment	307,	-
Depression (Psychiatric disorders)	20OCT2015	23NOV2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	308,	708
Insomnia (Psychiatric disorders)	28OCT2015		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	316,	-
Hypothyroidism (Endocrine disorders)	08NOV2015		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	327,	-
Hordeolum (Infections and infestations)	18JUL2016	20JUL2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	580,	582
Gastrooesophageal reflux disease (Gastrointestinal disorders)	25JUL2016	13NOV2016	No	Mild	Resolved, no sequalae	Not related	Not related	Other measures taken: gastroscopy	587,	698
Toothache (Gastrointestinal disorders)	30AUG2016	31AUG2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	623,	624

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 16DEC2014

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Back pain (Musculoskeletal and connective tissue disorders)	26SEP2016 /23:00	29SEP2016 /10:00	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Other measures taken: Red light therapy	650, 653
Abdominal infection (Infections and infestations)	23JAN2017	29JAN2017	No	Mild	Resolved, no sequalae	Not related	Not related	None	769, 775
Dizziness (Nervous system disorders)	20FEB2017	20FEB2017	No	Mild	Resolved, no sequalae	Not related	Not related	None	797, 797
Muscle tightness (Musculoskeletal and connective tissue disorders)	17MAY2017		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	883, -
Influenza (Infections and infestations)	23JUN2017	03JUL2017	No	Mild	Resolved, no sequalae	Not related	Not related	None	920, 930
Mental disorder (Psychiatric disorders)	15NOV2017	17NOV2017	No	Mild	Resolved, no sequalae	Not related	Not related	None	1065, 1067
Neurological examinatio n (Investigations)	30NOV2017	05DEC2017	No	Mild	Resolved, no sequalae	Not related	Not related	None	1080, 1085

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 16DEC2014

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Tension headache (Nervous system disorders)	04MAR2018		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment, Other measures taken: acupuncture	1174, -
Syncope (Nervous system disorders)	06SEP2018	06SEP2018	No	Mild	Resolved, no sequalae	Not related	Not related	None	1360, 1360
Urticaria (Skin and subcutaneous tissue disorders)	20NOV2018	05DEC2018	No	Moderate	Resolved, no sequalae	Not related	Not related	Other measures taken: Allergometry	1435, 1450
Bacterial infection (Infections and infestations)	16OCT2019	26OCT2019	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1765, 1775

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 20JAN2015

Date of implantation : 15APR2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
C-reactive protein in creased (Investigations)	23JAN2015 /07:43		No	Mild	Resolved, no sequalae	Related	Not related	None	3,	-
Nasopharyngitis (Infections and infestations)	14JUL2015 /12:00	21JUL2015	No	Moderate	Recovering/ Resolving	Not related	Not related	Specific drug treatment	175,	182
Erythema migrans (Infections and infestations)	--JUN2016	--JUL2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	527,	-
Hypothyroidism (Endocrine disorders)	01OCT2016		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	620,	-
Back pain (Musculoskeletal and connective tissue disorders)	--OCT2016	11MAR2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	650,	1146
Influenza (Infections and infestations)	--DEC2016	--JAN2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	711,	-
Tinnitus (Ear and labyrinth disorders)	--JAN2017		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	742,	-
Muscle spasms (Musculoskeletal and connective tissue disorders)	--FEB2017		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	770,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 20JAN2015

Date of implantation : 15APR2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Nasopharyngitis (Infections and infestations)	--OCT2017	--OCT2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1015, -
Sciatica (Nervous system disorders)	12MAR2018	25MAR2018	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1147, 1160
Sciatica (Nervous system disorders)	28MAR2018		No	Moderate		Not related	Not related	Specific drug treatment	1163, -
Nasopharyngitis (Infections and infestations)	27JUN2018	10JUL2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1254, 1267
Pharyngitis bacterial (Infections and infestations)	18NOV2018	27NOV2018	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1398, 1407
Helicobacter infectio n (Infections and infestations)	17FEB2019	28FEB2019	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1489, 1500
Helicobacter infectio n (Infections and infestations)	--SEP2019	--SEP2019	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1714, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=06/0610 Age=31 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 25JUN2015

Date of implantation : 08SEP2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Gastritis (Gastrointestinal disorders)	20AUG2015	22AUG2015	No	Severe	Resolved, no sequalae	Not related	Not related	Other measures taken: Gastroscoy	56,	58
Myalgia (Musculoskeletal and connective tissue disorders)	09SEP2015 /08:00	20SEP2015 /12:00	No	Moderate	Resolved, no sequalae	Related	Not related	Specific drug treatment	76,	87
Rhinitis (Infections and infestations)	10OCT2015 /12:00	23OCT2015 /12:00	No	Mild	Resolved, no sequalae	Not related	Not related	None	107,	120
Sciatica (Nervous system disorders)	08JAN2016 /10:00	14JAN2016 /09:00	Yes	Moderate	Recovering/ Resolving	Related	Not related	Specific drug treatment	197,	203
Intervertebral disc p rotusion reported as Rezidiv disc prolaps L5/S1 (Musculoskeletal and connective tissue disorders)	18JAN2016 /09:00	25JAN2016 /09:30	Yes	Moderate	Resolved, no sequalae	Related	Not related	Specific drug treatment, Subsequent surgical procedure: Nucleotomie, Neurolysis S1 left	207,	214
Panic attack (Psychiatric disorders)	07SEP2020 /13:00	07SEP2020 /13:30	No	Mild	Resolved, no sequalae	Not related	Not related	None	1901,	1901

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 15JUL2015

Date of implantation : 20OCT2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Sleep apnoea syndrome (Respiratory, thoracic and mediastinal disorders)	14OCT2015 /08:00	16OCT2015 /10:00	Yes	Moderate	Resolved, no sequalae	Not related	Not related	None	91,	93
Nasopharyngitis (Infections and infestations)	22DEC2015	27DEC2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	160,	165
Cataract (Eye disorders)	26JAN2016 /08:30	--MAR2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: cataract operation	195,	-
Cataract (Eye disorders)	10MAY2016 /09:00	10JUN2016 /10:00	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: cataract surgery	300,	331
Pain in extremity (Musculoskeletal and connective tissue disorders)	13MAY2016 /18:00	16MAY2016	No	Mild	Recovering/ Resolving	Not related	Not related	None	303,	306
Deep vein thrombosis (Vascular disorders)	16MAY2016 /10:00	20MAY2016 /10:00	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	306,	310

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 15JUL2015

Date of implantation : 20OCT2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Myasthenia gravis (Nervous system disorders)	03JAN2017		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: computertomography	538,	-
Nasopharyngitis (Infections and infestations)	02MAR2018	08MAR2018	No	Mild	Resolved, no sequelae	Not related	Not related	None	961,	967
Basal cell carcinoma (Neoplasms benign, malignant and unspecified (incl cysts and polyps))	29AUG2019	03SEP2019	No	Mild	Resolved, no sequelae	Not related	Not related	Subsequent surgical procedure: Excision ambulant	1506,	1511
Sciatica (Nervous system disorders)	14NOV2019	--DEC2019	No	Mild	Resolved, no sequelae	Related	Not related	Other measures taken: MRT	1583,	-
Nasopharyngitis (Infections and infestations)	12DEC2019	19DEC2019	No	Moderate	Resolved, no sequelae	Not related	Not related	Specific drug treatment	1611,	1618
Nasopharyngitis (Infections and infestations)	04SEP2020	13SEP2020	No	Moderate	Resolved, no sequelae	Not related	Not related	Specific drug treatment	1878,	1887

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=06/0613 Age=51 Sex=Male Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 20JUL2015

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Back pain (Musculoskeletal and connective tissue disorders)	13FEB2016	12MAR2016	No	Mild	Resolved, no sequalae	Not related	Not related	None	208, 236
Back pain (Musculoskeletal and connective tissue disorders)	--FEB2017	--SEP2019	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	589, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 18AUG2015

Date of implantation : 18NOV2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Sciatica (Nervous system disorders)	14NOV2015 /10:00	25NOV2015	No	Moderate	Resolved, no sequalae	Related	Not related	Specific drug treatment	88,	99
Influenza (Infections and infestations)	18DEC2015 /08:00	26DEC2015 /08:00	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	122,	130
Sciatica (Nervous system disorders)	25JAN2016	22FEB2016	No	Moderate	Not recovered/ Not resolved	Related	Related	Specific drug treatment	160,	188
Sciatica (Nervous system disorders)	22FEB2016	10MAR2016 /09:00	No	Moderate	Not recovered/ Not resolved	Related	Not related	Specific drug treatment, Other measures taken: 75.04	188,	205
Intervertebral disc p rotrusion reported as Rezidiv disc prolaps L5/S1 right side (Musculoskeletal and connective tissue disorders)	10MAR2016 /10:00	16MAR2016 /10:00	Yes	Moderate	Resolved, no sequalae	Related	Not related	Specific drug treatment, Subsequent surgical procedure: nucleotomy	205,	211
Sciatica (Nervous system disorders)	05JUL2016	10AUG2016 /09:00	No	Severe	Resolved, no sequalae	Related	Not related	Specific drug treatment	322,	358

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 18AUG2015

Date of implantation : 18NOV2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Intervertebral disc protrusion reported as /10:00 Rezidiv sequester L5 /S1 right side (Musculoskeletal and connective tissue disorders)	10AUG2016	18AUG2016 /11:28	Yes	Severe	Resolved, no sequelae	Related	Not related	Specific drug treatment, Subsequent surgical procedure: interbody-fusion L5/S1	358, 366
Nausea (Gastrointestinal disorders)	12AUG2016	13AUG2016	No	Mild	Resolved, no sequelae	Not related	Not related	Specific drug treatment	360, 361
Sciatica (Nervous system disorders)	18AUG2016 /11:30	28OCT2019	No	Mild	Resolved, no sequelae	Related	Not related	Specific drug treatment	366, 1532

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=06/0617 Age=33 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 22DEC2015

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Sciatica (Nervous system disorders)	01MAR2016	08MAR2016 /07:00	No	Moderate	Not recovered/ Not resolved	Related	Not related	None	70, 77
Intervertebral disc p rotrusion reported as Recurrence of disc h erniation L4/5 right side (Musculoskeletal and connective tissue disorders)	08MAR2016 /07:00		No	Moderate	Recovering/ Resolving	Related	Not related	None	77, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 23FEB2016

Date of implantation : 10MAY2016

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Cystitis (Infections and infestations)	--MAR2016	--MAY2016	No	Mild	Resolved, no sequalae	Not related	Not related	None	37,	-
Seasonal allergy (Immune system disorders)	12APR2016	23APR2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	49,	60
Sciatica (Nervous system disorders)	11MAY2016	02JUN2016	No	Moderate	Resolved, no sequalae	Related	Not related	Specific drug treatment	78,	100
Sacroiliac joint dysf unction (Musculoskeletal and connective tissue disorders)	01AUG2016	10AUG2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	160,	169
Sciatica (Nervous system disorders)	02NOV2016 /08:00	03NOV2016 /06:00	No	Mild	Resolved, no sequalae	Not related	Not related	None	253,	254
Tonsillitis (Infections and infestations)	03JAN2017	24JAN2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	315,	336
Depression (Psychiatric disorders)	25JUN2017		No	Severe	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	488,	-
Sciatica (Nervous system disorders)	28AUG2017	30OCT2017	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	552,	615

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 23FEB2016

Date of implantation : 10MAY2016

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Erysipelas (Infections and infestations)	23AUG2019	04SEP2019	Yes	Severe	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1277, 1289
COVID-19 (Infections and infestations)	--SEP2020	--OCT2020	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1681, -
Dysuria (Renal and urinary disorders)	11JAN2021	12JAN2021	Yes	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: functional myelography, CT	1784, 1785
Dysuria (Renal and urinary disorders)	13JAN2021		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	1786, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=06/0620 Age=27 Sex=Male Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 24FEB2016

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Seasonal allergy (Immune system disorders)	20MAY2016	03JUN2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	86, 100
Headache (Nervous system disorders)	--FEB2018	--FEB2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	735, -
Nasopharyngitis (Infections and infestations)	13MAR2018	15MAR2018	No	Mild	Resolved, no sequalae	Not related	Not related	None	748, 750
Nasopharyngitis (Infections and infestations)	02MAR2019	07MAR2019	No	Mild	Resolved, no sequalae	Not related	Not related	None	1102, 1107
Nasopharyngitis (Infections and infestations)	05NOV2019	07NOV2019	No	Mild	Resolved, no sequalae	Not related	Not related	None	1350, 1352
Seasonal allergy (Immune system disorders)	--MAY2020		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	1558, -
Sciatica (Nervous system disorders)	18SEP2020	27SEP2020	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Other measures taken: Physiotherapy	1668, 1677

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 06NOV2014

Date of implantation : 20JAN2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Gastroenteritis (Infections and infestations)	02OCT2018 /00:00	09OCT2018 /00:00	No	Moderate	Resolved, no sequalae	Not related	Not related	None	1426, 1433

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=07/0702 Age=32 Sex=Female Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 20JAN2015

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Hypokalaemia (Metabolism and nutrition disorders)	19JAN2015 /09:00	19JAN2015 /16:00	No	Moderate	Resolved, no sequaleae	Not related	Not related	Specific drug treatment	-1,	-2
Drug hypersensitivity (Immune system disorders)	22JAN2015 /08:00	22JAN2015 /12:00	No	Mild	Resolved, no sequaleae	Not related	Not related	Specific drug treatment	2,	2
Depression (Psychiatric disorders)	14JUN2015		No	Mild	Recovering/ Resolving	Not related	Not related	Specific drug treatment	145,	-
Road traffic accident (Injury, poisoning and procedural complications)	03SEP2017 /10:00		No	Moderate	Recovering/ Resolving	Not related	Not related	Specific drug treatment	957,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 03MAR2015

Date of implantation : 19MAY2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Toothache (Gastrointestinal disorders)	18JUN2015	18JUN2015	No	Moderate	Resolved, no sequalae	Not related	Not related	Other measures taken: Ibuprofen	107,	107
Asthma (Respiratory, thoracic and mediastinal disorders)	--SEP2015	--DEC2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	211,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 16JUL2015

Date of implantation : 08OCT2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Procedural nausea (Injury, poisoning and procedural complications)	16JUL2015 /18:00	16JUL2015 /21:30	No	Mild	Resolved, no sequalae	Related	Not related	Specific drug treatment	0,	0
Procedural vomiting (Injury, poisoning and procedural complications)	16JUL2015 /18:00	16JUL2015 /21:30	No	Mild	Resolved, no sequalae	Related	Not related	Specific drug treatment	0,	0
Influenza (Infections and infestations)	06JUN2019 /12:00	14JUN2019 /00:00	No	Moderate	Resolved, no sequalae	Not related	Not related	None	1421,	1429

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=08/0801 Age=51 Sex=Female Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 03NOV2014

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Musculoskeletal pain (Musculoskeletal and connective tissue disorders)	20APR2015		No	Mild	Lost to follow-up	Not related	Not related	None	168, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 27NOV2014

Date of implantation : 04MAR2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Migraine (Nervous system disorders)	15MAY2015 /00:00	15MAY2015 /09:00	No	Moderate	Resolved with sequelae: recurrent 1x/month	Not related	Not related	Specific drug treatment	169, 169
Spinal pain (Musculoskeletal and connective tissue disorders)	03DEC2015 /00:00	15JAN2016 /00:00	No	Moderate	Resolved, no sequelae	Not related	Not related	Specific drug treatment, Other measures taken: physiotherapy	371, 414
Muscle rupture (Injury, poisoning and procedural complications)	30DEC2015 /00:00	14FEB2016 /00:00	No	Mild	Resolved, no sequelae	Not related	Not related	Other measures taken: physiotherapy	398, 444
Toothache (Gastrointestinal disorders)	20FEB2016 /00:00	25FEB2016 /23:59	No	Mild	Resolved, no sequelae	Not related	Not related	Other measures taken: professional tooth cleaning	450, 455
Spinal pain (Musculoskeletal and connective tissue disorders)	--DEC2016		No	Mild	Not recovered/ Not resolved	Not related	Not related	Other measures taken: Physiotherapy, massage	765, -
Migraine (Nervous system disorders)	02JAN2017 /00:00		No	Mild	Recovering/ Resolving	Not related	Not related	Specific drug treatment	767, -
Carpal tunnel syndrome (Nervous system disorders)	23NOV2017 /00:00	15DEC2017 /00:00	No	Moderate	Resolved, no sequelae	Not related	Not related	Subsequent surgical procedure: surgery 23. Nov. 2017	1092, 1114

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 27NOV2014

Date of implantation : 04MAR2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Arthritis (Musculoskeletal and connective tissue disorders)	--FEB2020	--FEB2020	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1919, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=08/0803 Age=51 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 25FEB2015

Date of implantation : 16JUN2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Procedural headache (Injury, poisoning and procedural complications)	16JUN2015	26JUN2015	No	Moderate	Resolved, no sequelae	Related	Not related	Specific drug treatment	111, 121

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 03JUN2015

Date of implantation : 21AUG2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Sleep disorder (Psychiatric disorders)	05JUN2015 /23:00	05JUN2015 /23:59	No	Mild	Resolved, no sequalae	Related	Not related	Specific drug treatment	2,	2
Headache (Nervous system disorders)	20DEC2015 /00:00	26DEC2015 /00:00	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	200,	206
Back pain (Musculoskeletal and connective tissue disorders)	21JUL2017 /00:00	15AUG2017 /23:59	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	779,	804
Gastrointestinal infection (Infections and infestations)	01FEB2019	07FEB2019	No	Mild	Resolved, no sequalae	Not related	Not related	None	1339,	1345

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 25JUN2015

Date of implantation : 22SEP2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Procedural pain (Injury, poisoning and procedural complications)	01OCT2015 /07:00	10DEC2015 /23:59	No	Mild	Resolved, no sequelae	Related	Related	Specific drug treatment	98, 168
Pain in extremity (Musculoskeletal and connective tissue disorders)	12JUN2016 /00:00	27JUL2016	No	Moderate	Resolved with sequelae: persistent paresis	Related	Related	Specific drug treatment	353, 398
Monoparesis (Nervous system disorders)	12JUN2016 /00:00	27JUL2016	No	Moderate	Resolved with sequelae: persistent paresis	Related	Related	Specific drug treatment	353, 398
Arthropod bite (Injury, poisoning and procedural complications)	06JUL2016 /17:30	01AUG2016 /20:00	No	Mild	Resolved, no sequelae	Not related	Not related	None	377, 403
Erythema migrans (Infections and infestations)	06JUL2016 /17:30	01AUG2016 /20:00	No	Mild	Resolved, no sequelae	Not related	Not related	Specific drug treatment	377, 403

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 25JUN2015

Date of implantation : 22SEP2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Intervertebral disc protrusion reported as recurrence disc herniation L2/L3 (Musculoskeletal and connective tissue disorders)	28JUL2016 /08:00	01AUG2016 /14:00	Yes	Moderate	Resolved, no sequelae	Related	Related	Specific drug treatment, Subsequent surgical procedure: Nucleotomy L2/3 right 28/JUL/16, Other measures taken: Physiotherapy. Electrophysiological examination	399, 403
Upper respiratory tract infection (Infections and infestations)	15JAN2017 /00:00	18JAN2017 /00:00	No	Mild	Resolved, no sequelae	Not related	Not related	None	570, 573
Paraesthesia (Nervous system disorders)	15AUG2017 /14:00	15AUG2017 /23:59	No	Mild	Resolved, no sequelae	Related	Related	Specific drug treatment	782, 782
Dental implantation (Surgical and medical procedures)	01APR2018 /00:00	07APR2018 /00:00	No	Moderate	Resolved, no sequelae	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: dental implants	1011, 1017
Cartilage injury (Injury, poisoning and procedural complications)	01JUN2018 /00:00		No	Mild	Recovering/ Resolving	Not related	Not related	Specific drug treatment, Other measures taken: physiotherapy	1072, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 25JUN2015

Date of implantation : 22SEP2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Depression (Psychiatric disorders)	01JUN2018 /00:00		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	1072,	-
Varicose vein (Vascular disorders)	01NOV2018	01NOV2018	No	Mild	Resolved, no sequelae	Not related	Not related	Subsequent surgical procedure: surgery	1225, 1225	
Dental implantation (Surgical and medical procedures)	01MAR2019	07MAR2019	No	Moderate	Resolved, no sequelae	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: dental implants	1345, 1351	
Meniscus injury (Injury, poisoning and procedural complications)	15FEB2020	16FEB2020	Yes	Severe	Resolved with sequelae: surgery 15. FEB 2020. Another surgery is planned.	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: endoscopic surgery is done. 2nd surgery is planned, Other measures taken: physiotherapy	1696, 1697	

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 08JUL2015

Date of implantation : 29SEP2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Gastritis (Gastrointestinal disorders)	12JUL2015 /18:00	31JUL2015 /23:59	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	4, 23
Nasopharyngitis (Infections and infestations)	15OCT2015 /00:00	20OCT2015 /00:00	No	Mild	Resolved, no sequalae	Not related	Not related	None	99, 104
Headache (Nervous system disorders)	01DEC2015	02DEC2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	146, 147
Nasopharyngitis (Infections and infestations)	28DEC2015 /00:00	29DEC2015 /00:00	No	Mild	Resolved, no sequalae	Not related	Not related	None	173, 174
Headache (Nervous system disorders)	25FEB2016 /18:00	26FEB2016 /00:00	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	232, 233
Depression (Psychiatric disorders)	05JUN2017		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment, Other measures taken: Psychotherapy	698, -
Anxiety disorder (Psychiatric disorders)	06JUN2017		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment, Other measures taken: Psycotherapy	699, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 08JUL2015

Date of implantation : 29SEP2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Arthralgia (Musculoskeletal and connective tissue disorders)	10JUL2017	20JUL2017	No	Mild	Resolved, no sequalee	Not related	Not related	Other measures taken: Shoe inlays (splay feet)	733,	743
Meniscus injury (Injury, poisoning and procedural complications)	01NOV2019		No	Mild	Not recovered/ Not resolved	Not related	Not related	Other measures taken: physiotherapy	1577,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=08/0807 Age=48 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 19NOV2015

Date of implantation : 02FEB2016

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Sleep disorder (Psychiatric disorders)	18NOV2015 /22:45	24NOV2015 /08:00	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	-1,	5
Hypertension (Vascular disorders)	15DEC2015 /00:00	01FEB2016 /10:00	No	Mild	Resolved with sequelae: resolved with new medication	Not related	Not related	Specific drug treatment	26,	74
Nasopharyngitis (Infections and infestations)	17FEB2016 /00:00	29FEB2016 /23:59	No	Mild	Resolved, no sequelae	Not related	Not related	None	90,	102
Sciatica (Nervous system disorders)	03MAR2016 /19:00	16MAR2016 /23:59	No	Mild	Resolved, no sequelae	Related	Not related	Specific drug treatment	105,	118
Hypertension (Vascular disorders)	03MAY2016 /00:00	01JUL2016 /00:00	No	Mild	Resolved, no sequelae	Not related	Not related	None	166,	225
Blood pressure increa sed (Investigations)	15DEC2016 /00:00	19FEB2018	No	Mild	Resolved, no sequelae	Not related	Not related	Specific drug treatment	392,	823
Sciatica (Nervous system disorders)	--SEP2017 /00:00		No	Mild	Not recovered/ Not resolved	Related	Related	Other measures taken: physiotherapy	681,	-
Adverse drug reaction (General disorders and administration site conditions)	16OCT2017	19FEB2018	No	Moderate	Resolved, no sequelae	Not related	Not related	Specific drug treatment	697,	823

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=08/0808 Age=57 Sex=Male Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 03DEC2015

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Sleep disorder (Psychiatric disorders)	06DEC2015 /23:00	07DEC2015 /23:59	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	3,	4
Nasopharyngitis (Infections and infestations)	05JAN2016 /00:00	11JAN2016 /00:00	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	33,	39
Back pain (Musculoskeletal and connective tissue disorders)	23APR2016 /00:00	30APR2016 /00:00	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Other measures taken: acupuncture (spinal non drug th.)	142,	149
Sciatica (Nervous system disorders)	23APR2016 /00:00	30APR2016 /00:00	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Other measures taken: acupuncture (spinal kon drug th.)	142,	149
Gastrointestinal moti lity disorder (Gastrointestinal disorders)	27MAR2017	19APR2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	480,	503
Back pain (Musculoskeletal and connective tissue disorders)	27MAR2017	19APR2017	No	Mild	Resolved, no sequalae	Related	Not related	Specific drug treatment, Other measures taken: Acupuncture	480,	503
Hypercholesterolaemia (Metabolism and nutrition disorders)	18SEP2017		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	655,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=08/0808 Age=57 Sex=Male Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 03DEC2015

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Anaphylactic reaction (Immune system disorders)	13JUN2018	13JUN2018	No	Mild	Resolved with sequelae: planned allergic desensitization	Not related	Not related	Specific drug treatment	923, 923
Back pain (Musculoskeletal and connective tissue disorders)	29JUN2018	30JUN2018	No	Mild	Resolved, no sequelae	Related	Not related	Other measures taken: accupuncture / massage	939, 940
Back pain (Musculoskeletal and connective tissue disorders)	20AUG2018	20AUG2018	No	Mild	Resolved, no sequelae	Related	Not related	None	991, 991
Myalgia (Musculoskeletal and connective tissue disorders)	20AUG2018	20AUG2018	No	Mild	Resolved, no sequelae	Not related	Not related	None	991, 991
Immune tolerance induction (Surgical and medical procedures)	12DEC2018	14DEC2018	Yes	Mild	Resolved with sequelae: another desensitization is planned 6/19	Not related	Not related	Specific drug treatment	1105, 1107

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=09/0901 Age=48 Sex=Male Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 30OCT2014

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Back pain (Musculoskeletal and connective tissue disorders)	15MAR2017	10SEP2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	867, 1046
Arrhythmia (Cardiac disorders)	10JAN2019	22MAY2019	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1533, 1665

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=09/0903 Age=54 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 20NOV2014

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Back pain (Musculoskeletal and connective tissue disorders)	20JAN2015	01FEB2015	No	Moderate	Resolved, no sequelae	Not related	Not related	Specific drug treatment	61,	73
Bacterial disease car rier (Infections and infestations)	11FEB2015 /14:05		No	Mild	Unknown	Not related	Not related	None	83,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 09FEB2015

Date of implantation : 21MAY2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Arthralgia (Musculoskeletal and connective tissue disorders)	28AUG2015	30APR2016	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	200,	446
Ligament rupture (Injury, poisoning and procedural complications)	18MAR2016 /06:50	02MAY2016	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Other measures taken: Aircast - brace	403,	448
Cervical spinal steno- sis (Musculoskeletal and connective tissue disorders)	26SEP2016		No	Moderate	Recovering/ Resolving	Not related	Not related	Specific drug treatment	595,	-
Benign prostatic hyper- plasia (Reproductive system and breast disorders)	08NOV2016		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	638,	-
Sciatica (Nervous system disorders)	28FEB2020	20MAR2020	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1845,	1866

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 19MAR2015

Date of implantation : 25JUN2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Back pain (Musculoskeletal and connective tissue disorders)	21MAR2015	19APR2015	No	Moderate	Resolved, no sequalae	Related	Not related	Specific drug treatment	2,	31
Nasal polyps (Respiratory, thoracic and mediastinal disorders)	21SEP2015	24SEP2015	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	186,	189
Intervertebral disc p rotrusion reported as Recurrent lumbar dis herniation L4/L5 righ (Musculoskeletal and connective tissue disorders)	01SEP2018	--SEP2019	No	Moderate	Not recovered/ Not resolved	Related	Not related	Specific drug treatment	1262,	-
Intervertebral disc p rotrusion reported as Recurrent lumbar dis c herniation L4/L5 re (Musculoskeletal and connective tissue disorders)	10MAR2019	15MAR2019	Yes	Severe	Recovering/ Resolving	Related	Not related	Specific drug treatment, Subsequent surgical procedure: reoperation	1452,	1457

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=09/0907 Age=58 Sex=Male Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 15APR2015

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Diverticulitis (Infections and infestations)	05OCT2016	14OCT2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	539, 548
Arthralgia (Musculoskeletal and connective tissue disorders)	23SEP2018	13NOV2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1257, 1308

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 12MAY2015

Date of implantation : 13AUG2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Sciatica (Nervous system disorders)	15AUG2015 /18:00	20AUG2015	No	Moderate	Resolved, no sequalae	Related	Related	Specific drug treatment	95, 100
Anaemia (Blood and lymphatic system disorders)	01OCT2015	22DEC2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	142, 590
Anaemia (Blood and lymphatic system disorders)	01OCT2015	22DEC2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	142, 590
Gastritis (Gastrointestinal disorders)	02NOV2015 /12:00	01FEB2016	No	Mild	Resolved, no sequalae	Not related	Not related	Other measures taken: Gastroscoy in analgo sedation	174, 265
Cervicobrachial syndr ome (Nervous system disorders)	14JUL2016		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	429, -
Periarthritis (Musculoskeletal and connective tissue disorders)	18NOV2017	02APR2019	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Other measures taken: Physical Therapy	921, 1421
Diastolic dysfunction (Cardiac disorders)	11OCT2019		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	1613, -
Diastolic dysfunction (Cardiac disorders)	23OCT2019	24OCT2019	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1625, 1626

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 19OCT2015

Date of implantation : 14JAN2016

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Renal colic (Renal and urinary disorders)	06MAY2016	17MAY2016	Yes	Severe	Resolved, no sequelae	Not related	Not related	Specific drug treatment, Other measures taken: ureter catheter	200,	211
Urinary tract infection (Infections and infestations)	06MAY2016	17MAY2016	Yes	Severe	Resolved, no sequelae	Not related	Not related	Specific drug treatment, Other measures taken: Ureter catheter	200,	211
Back pain (Musculoskeletal and connective tissue disorders)	13NOV2016	23NOV2016	No	Moderate	Resolved, no sequelae	Not related	Not related	Specific drug treatment	391,	401
Ureteric stenosis (Renal and urinary disorders)	03SEP2017 /01:00		Yes	Severe	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: inserting o ureter splint	685,	-
Urinary tract infection (Infections and infestations)	03SEP2017 /01:00	04SEP2017 /10:00	No	Severe	Resolved, no sequelae	Not related	Not related	None	685,	686
Urinary tract infection (Infections and infestations)	29SEP2017	17OCT2017	No	Severe	Resolved, no sequelae	Not related	Not related	Specific drug treatment	711,	729

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 19OCT2015

Date of implantation : 14JAN2016

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Ureteric stenosis (Renal and urinary disorders)	29SEP2017	17OCT2017	Yes	Severe	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: Pyeloplasty right	711, 729
Cervical incompetence (Pregnancy, puerperium and perinatal conditions)	23SEP2020	30SEP2020	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1801, 1808
Vulvovaginal mycotic infection (Infections and infestations)	23SEP2020	27SEP2020	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1801, 1805
Urinary tract infecti on (Infections and infestations)	23SEP2020	27SEP2020	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1801, 1805
Arrested labour (Pregnancy, puerperium and perinatal conditions)	01JAN2021	05JAN2021	Yes	Severe	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: Sectio	1901, 1905

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 20OCT2015

Date of implantation : 21JAN2016

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Back pain (Musculoskeletal and connective tissue disorders)	22JAN2016 /08:00	28JAN2016 /08:00	Yes	Moderate	Resolved, no sequalae	Related	Related	Specific drug treatment	94, 100
Meniscus injury (Injury, poisoning and procedural complications)	13JUL2018	22JUL2018	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: Athroskopie re Knee 20.07.18	997, 1006
Bladder irritation (Renal and urinary disorders)	07AUG2018		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	1022, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 30NOV2015

Date of implantation : 18FEB2016

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Dysaesthesia (Nervous system disorders)	03DEC2015	05DEC2015	No	Mild	Resolved, no sequalae	Related	Not related	Specific drug treatment	3,	5
Procedural pain (Injury, poisoning and procedural complications)	07DEC2015	05FEB2016	No	Mild	Resolved, no sequalae	Related	Not related	Specific drug treatment	7,	67
Noninfective sialoadenitis (Gastrointestinal disorders)	12JUL2016	17JUL2016	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	225,	230
Back pain (Musculoskeletal and connective tissue disorders)	24JAN2017 /06:00	27JAN2017 /20:00	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	421,	424
Depression (Psychiatric disorders)	27NOV2017		No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	728,	-
Depression (Psychiatric disorders)	05FEB2019	19MAR2019	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Other measures taken: in patient psychosomatic rehabilitation	1163,	1205

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=09/0914 Age=35 Sex=Male Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 06JAN2016

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Chronic sinusitis (Infections and infestations)	13APR2016	16JUL2016	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	98, 192
Varicose vein (Vascular disorders)	30NOV2016	08DEC2016	Yes	Moderate	Resolved, no sequalae	Not related	Not related	None, Subsequent surgical procedure: Varicosis surgery 30Nov2016	329, 337

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 06JAN2016

Date of implantation : 24MAR2016

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Procedural pain (Injury, poisoning and procedural complications)	24MAR2016 /22:00	25MAR2016	No	Mild	Resolved, no sequalae	Related	Not related	Specific drug treatment	78, 79
Back pain (Musculoskeletal and connective tissue disorders)	12DEC2016 /12:00	05JAN2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Other measures taken: massage	341, 365
Back pain (Musculoskeletal and connective tissue disorders)	15DEC2017	26FEB2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	709, 782
Intervertebral disc p rotrusion reported as Rezidiv Prolaps L4 L 5 re (Musculoskeletal and connective tissue disorders)	14JUL2020	30OCT2020	No	Moderate	Resolved, no sequalae	Related	Related	Specific drug treatment, Other measures taken: Physiotherapie	1651, 1759

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=09/0916 Age=57 Sex=Male Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 23FEB2016

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Atrial fibrillation (Cardiac disorders)	23FEB2016 /11:10	17MAR2016	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	0, 23
Back pain (Musculoskeletal and connective tissue disorders)	02MAR2016	15MAR2016	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	8, 21
Intraocular lens impl ant (Surgical and medical procedures)	07SEP2016	08SEP2016	Yes	Moderate	Resolved, no sequalae	Not related	Not related	None	197, 198
Pneumonia (Infections and infestations)	18NOV2016		Yes	Severe	Resolved, no sequalae	Not related	Not related	Specific drug treatment	269, -
Back pain (Musculoskeletal and connective tissue disorders)	03OCT2017	01DEC2017	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	588, 647

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 13JAN2015

Date of implantation : 31MAR2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Back pain (Musculoskeletal and connective tissue disorders)	01OCT2015	--NOV2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	261,	-
Arthralgia (Musculoskeletal and connective tissue disorders)	--FEB2016	--SEP2016	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	411,	-
Vulvovaginal pain (Reproductive system and breast disorders)	--FEB2016	--MAY2016	No	Mild	Resolved, no sequalae	Not related	Not related	None	411,	-
Sciatica (Nervous system disorders)	--JAN2017	27SEP2017	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Other measures taken: physiotherapy p.76.02	749,	988
Intervertebral disc p rotrusion reported as Relapse L5/S1 (Musculoskeletal and connective tissue disorders)	27SEP2017	29SEP2017	Yes	Severe	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: RE-EILF (extended interlaminar fenestration) L5/S1 left sideed	988,	990

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 13JAN2015

Date of implantation : 31MAR2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Sciatica (Nervous system disorders)	30SEP2017	--JUN2019	No	Mild	Recovering/ Resolving	Not related	Not related	Specific drug treatment, Other measures taken: MRI + X-RAY 21/03/2018 - ct-assisted periradicular therapy, ambulant: 26/MAR/2018 nerve root S1 left side	991, -
Idiopathic generalise d epilepsy (Nervous system disorders)	12NOV2017	16NOV2017	Yes	Severe	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1034, 1038
Vitamin D deficiency (Metabolism and nutrition disorders)	--OCT2018	--OCT2018	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	1387, -
Sciatica (Nervous system disorders)	--JUN2019	30JUL2019 /10:02	No	Severe	Recovering/ Resolving	Not related	Not related	Specific drug treatment, Other measures taken: MRI taken on 23/JUL/2019	1629, 1659
Intervertebral disc p rotrusion reported as Relapse L5/S1 left (Musculoskeletal and connective tissue disorders)	30JUL2019 /10:02	03AUG2019 /13:59	Yes	Severe	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: TLIF (transforaminale lumbar at interbody fusion L5/S1	1659, 1663

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 13JAN2015

Date of implantation : 31MAR2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Back pain (Musculoskeletal and connective tissue disorders)	11APR2020		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	1915, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 20APR2015

Date of implantation : 28JUL2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Procedural pain (Injury, poisoning and procedural complications)	28JUL2015 /15:UNK	28JUL2015 /15:37	No	Severe	Resolved, no sequelae	Related	Not related	Other measures taken: transplantation was stopped	99, 99

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 03AUG2015

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Post procedural haemo rrhage (Injury, poisoning and procedural complications)	04AUG2015	14AUG2015	Yes	Severe	Resolved, no sequalae	Related	Not related	Specific drug treatment, Subsequent surgical procedure: surgical removal of the epidural haemorrhage on 7th august 2015	1, 11
Procedural pain (Injury, poisoning and procedural complications)	14AUG2015	23NOV2015	No	Moderate	Resolved, no sequalae	Related	Not related	Specific drug treatment	11, 112
Hypertension (Vascular disorders)	25AUG2015		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	22, -
Chronic fatigue syndr ome (General disorders and administration site conditions)	--MAR2016	05AUG2016	No	Moderate	Resolved, no sequalae	Not related	Not related	None	241, 368
Pain in extremity (Musculoskeletal and connective tissue disorders)	--JAN2017	03JAN2018	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Other measures taken: MRI was taken (ambulant)	547, 884

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 03AUG2015

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Hypoaesthesia (Nervous system disorders)	--DEC2017	03JAN2018 /18:12	No	Severe	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: RE-ILF (interlaminar fenestration LWU5/SWU1 left	881, 884
Chronic fatigue syndr ome (General disorders and administration site conditions)	--DEC2017		No	Mild	Not recovered/ Not resolved	Not related	Not related	Other measures taken: amb. visitation sleep laboratory Dec 2017	881, -
Muscular weakness (Musculoskeletal and connective tissue disorders)	--DEC2017	--AUG2018 /18:12	No	Severe	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: RE-ILF (interlaminarfenestr ation L5/S1 left	881, -
Intervertebral disc p rotrusion reported as Relapse L5/S1 (Musculoskeletal and connective tissue disorders)	03JAN2018 /18:12	16JAN2018 /13:15	Yes	Severe	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Subsequent surgical procedure: RE-IFL (interlaminar fenestration) L5/S1 left sided 5Jan2018+10Jan2018	884, 897

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 03AUG2015

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Pain in extremity (Musculoskeletal and connective tissue disorders)	16JAN2018 /13:15	13FEB2018 /18:55	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	897, 925
Facet joint syndrome (Musculoskeletal and connective tissue disorders)	13FEB2018 /18:55	01MAR2018 /11:00	Yes	Severe	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Other measures taken: Facet joint infiltration LWU5/SWU1 left side periradicular therapy of the nerve root L5	925, 941
Pain in extremity (Musculoskeletal and connective tissue disorders)	01MAR2018 /11:00	--OCT2019	No	Moderate	Resolved, no sequalae	Not related	Not related	Specific drug treatment	941, -
Hypersomnia (Nervous system disorders)	25JUN2018 /11:28	28JUN2018 /13:51	Yes	Severe	Resolved, no sequalae	Not related	Not related	Specific drug treatment, Other measures taken: Monitoring in the sleep laboratory	1057, 1060
Hypersomnia (Nervous system disorders)	28JUN2018 /13:52		No	Severe	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	1060, -
Autoimmune thyroiditi s (Endocrine disorders)	--SEP2018		No	Mild	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment	1154, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 07MAR2016

Date of implantation : 08JUN2016

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Post procedural constipation (Injury, poisoning and procedural complications)	09MAR2016	12MAR2016	No	Mild	Resolved, no sequelae	Related	Not related	Specific drug treatment	2,	5
Cystitis (Infections and infestations)	06APR2016	14APR2016	No	Mild	Resolved, no sequelae	Not related	Not related	Specific drug treatment	30,	38
Back pain (Musculoskeletal and connective tissue disorders)	--NOV2019	--DEC2019	No	Mild	Resolved, no sequelae	Not related	Not related	Specific drug treatment	1363,	-
Haematochezia (Gastrointestinal disorders)	--DEC2019	22JAN2020	No	Moderate	Resolved, no sequelae	Not related	Not related	Other measures taken: colonoscopy	1394,	1416

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 07SEP2015

Date of implantation : 01DEC2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Eye pain (Eye disorders)	07SEP2015	--SEP2015	No	Mild	Resolved, no sequalae	Not related	Not related	Specific drug treatment	0,	-
Back pain (Musculoskeletal and connective tissue disorders)	22OCT2015	--NOV2015	No	Mild	Resolved, no sequalae	Not related	Not related	Other measures taken: x-Ray Thorax	45,	-
Procedural pain (Injury, poisoning and procedural complications)	01DEC2015 /20:56	26FEB2016 /09:00	Yes	Severe	Resolved, no sequalae	Related	Not related	Specific drug treatment	85,	172
Cartilage injury (Injury, poisoning and procedural complications)	14JAN2016		No	Moderate	Recovering/ Resolving	Not related	Not related	None	129,	-
Fall (Injury, poisoning and procedural complications)	14JAN2016	14JAN2016	No	Moderate	Resolved, no sequalae	Not related	Not related	None	129,	129
Synovitis (Musculoskeletal and connective tissue disorders)	--JAN2016	03SEP2016	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: Synevectomia (planned in hospitalization)	146,	362

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 07SEP2015

Date of implantation : 01DEC2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Bursitis (Musculoskeletal and connective tissue disorders)	--JAN2016	03SEP2016	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Subsequent surgical procedure: bursectomia arthroscopic (planned in hospitalization)	146,	362
Back pain (Musculoskeletal and connective tissue disorders)	14MAY2016		No	Severe	Not recovered/ Not resolved	Not related	Not related	None	250,	-
Back pain (Musculoskeletal and connective tissue disorders)	18MAY2016 /08:09	21MAY2016 /16:04	Yes	Severe	Resolved, no sequalae	Not related	Not related	Specific drug treatment	254,	257
Depression (Psychiatric disorders)	18MAY2016 /15:12		No	Moderate	Recovering/ Resolving	Not related	Not related	Specific drug treatment	254,	-
Intervertebral disc p rotrusion reported as prolaps lumbar disc LWK5/SWK1 (Musculoskeletal and connective tissue disorders)	22NOV2016	21NOV2017	No	Mild	Resolved, no sequalae	Related	Related	None	442,	806

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 07SEP2015

Date of implantation : 01DEC2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Facet joint syndrome (Musculoskeletal and connective tissue disorders)	--JUN2017	16DEC2019	No	Moderate	Not recovered/ Not resolved	Not related	Not related	Specific drug treatment, Other measures taken: Thermoablation facett joints LS	662, 1561
Contusion (Injury, poisoning and procedural complications)	26JUL2017		No	Mild	Resolved, no sequalae	Not related	Not related	None	688, -
Sacroiliac joint dysf unction (Musculoskeletal and connective tissue disorders)	--APR2018	19DEC2018	No	Moderate	Resolved, no sequalae	Related	Not related	Specific drug treatment, Other measures taken: Infiltration	966, 1199
Muscle rupture (Injury, poisoning and procedural complications)	14JUL2018	--AUG2018	No	Mild	Resolved, no sequalae	Not related	Not related	Other measures taken: Stack'sche Schiene	1041, -
Foot fracture (Injury, poisoning and procedural complications)	--SEP2018	22JAN2019	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Other measures taken: surgery, osteosynthesis	1119, 1233
Radiculopathy (Nervous system disorders)	17DEC2018	19DEC2018	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Other measures taken: thermodenervation ISG right	1197, 1199

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 07SEP2015

Date of implantation : 01DEC2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Sacroiliac joint dysf unction (Musculoskeletal and connective tissue disorders)	22JAN2019	25JAN2019	Yes	Moderate	Resolved, no sequalae	Not related	Not related	Other measures taken: thermodenervation left ISG	1233, 1236
Osteoarthritis (Musculoskeletal and connective tissue disorders)	--JAN2019		No	Moderate	Not recovered/ Not resolved	Not related	Not related	Other measures taken: Radiation	1242, -
Rotator cuff syndrome (Musculoskeletal and connective tissue disorders)	--SEP2019	01OCT2019	No	Moderate	Resolved, no sequalae	Not related	Not related	Other measures taken: Arthroscopy shoulder joint left	1484, 1485

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 27APR2015

Date of implantation : 29JUL2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Dizziness (Nervous system disorders)	11JUN2015	08SEP2015	No	Moderate	Resolved, no sequelae	Not related	Not related	None	45, 134
Vomiting (Gastrointestinal disorders)	28JUL2015	28JUL2015	No	Moderate	Resolved, no sequelae	Not related	Not related	None	92, 92
Sciatica (Nervous system disorders)	20MAR2017 /09:43	24MAR2017 /14:00	Yes	Moderate	Resolved, no sequelae	Related	Not related	Specific drug treatment, Other measures taken: physiotherapy	693, 697
Hyperaesthesia (Nervous system disorders)	20MAR2017 /09:43	24MAR2017 /14:00	Yes	Moderate	Resolved, no sequelae	Related	Not related	Specific drug treatment, Other measures taken: physiotherapy	693, 697
Neuropathy peripheral (Nervous system disorders)	--JAN2020	--FEB2020	No	Moderate	Resolved with sequelae: seldom recurrence of event	Not related	Not related	Specific drug treatment	1740, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment Arm=ND plus Planned Treatment Arm=ND plus

Date of sequestrectomy : 12MAY2015

Date of implantation : 29JUL2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Influenza (Infections and infestations)	-----2018	-----2018	No	Moderate	Resolved, no sequaleae	Not related	Not related	None	1329, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=13/1303 Age=31 Sex=Male Actual Treatment Arm=SC Planned Treatment Arm=SC

Date of sequestrectomy : 29JUN2015

Date of implantation : -

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)
Respiratory tract infection (Infections and infestations)	08JUN2016	29JUN2016	No	Moderate	Resolved, no sequelae	Not related	Not related	None	345, 366
Hyperaesthesia (Nervous system disorders)	01DEC2017	03JUN2020	No	Mild	Resolved, no sequelae	Related	Not related	Specific drug treatment	886, 1801
Muscle tightness (Musculoskeletal and connective tissue disorders)	20MAY2020 /12:00		No	Moderate	Not recovered/ Not resolved	Not related	Not related	None	1787, -

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.1: Adverse Events - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment Arm=ND basic Planned Treatment Arm=ND basic

Date of sequestrectomy : 02JUL2015

Date of implantation : 18SEP2015

Preferred Term (System Organ Class)	AE Start date/time	AE End date/time	Seriousness	Severity	Outcome(Date of Death)	Relationship to Medical Intervention	Relationship to Investigational Product	Countermeasure taken	Time from explant to AE start, AE end (days)	
Muscle tightness (Musculoskeletal and connective tissue disorders)	--JUL2016	--SEP2016	No	Mild	Resolved, no sequalae	Not related	Not related	Other measures taken: physiotherapy	395,	-
Sciatica (Nervous system disorders)	--FEB2018	--APR2018	No	Moderate	Resolved, no sequalae	Related	Related	Specific drug treatment	972,	-
Ligament sprain (Injury, poisoning and procedural complications)	--JAN2019	--FEB2019	No	Mild	Resolved, no sequalae	Not related	Not related	None	1309,	-

In case of not yet coded terms the reported term is used

For calculation of time from explant to Adverse Event start day missing Adverse Event start date was set to 1 and missing month was set to January in case of incomplete dates.

Clinipace: 14DEC21 / 7:42 / l_ae.lst / l_ae.sas

Listing 16.2.3.2: Subjects with adverse event 'intervertebral disc protrusion' (preferred term) - all enrolled subjects

Site/ Subject ID	Treat- ment Group	Analysis Set	Reported Term	Date of		AE Start date/time	Serious -ness	Location (Screening)		Outcome MRI 'Dorsal disc extrusion' Visit 3a		
				Sequest- rectomy	Implant- ation			herniated disc	adjacent disc	Central	Cranial not trt.	Cranial add.trt. Caudal
01-0104	NDisc basic	ES/SAF/FAS	herniated disc LWK 4/5	24OCT2012	22JAN2013	31JUL2013	No	L5 and S1 Right		No		No
01-0112	NDisc basic	ES/SAF	recurrent herniation of lumbal discus	26MAR2013		02APR2013	Yes	L5 and S1 Right				
01-0113	NDisc basic	ES/SAF/FAS	REHERNIATION	23MAY2013	06AUG2013	04AUG2014	Yes	L5 and S1 Left		Yes	No	
01-0118	NDisc plus	ES/SAF/FAS	reherniation	10JUL2013	08OCT2013	08JUL2014	Yes	L5 and S1 Left		No	No	
	NDisc plus	ES/SAF/FAS	REHERNIATION	10JUL2013	08OCT2013	25MAR2014	No	L5 and S1 Left		No	No	
	NDisc plus	ES/SAF/FAS	discus prolaps L5/S1 left	10JUL2013	08OCT2013	24MAY2016	No	L5 and S1 Left		No	No	
01-0123	NDisc plus	ES/SAF/FAS	DISC HERNIATION C6/7 left	16SEP2014	19DEC2014	--NOV2016	No	L4 and L5 Right		No	No	No
	NDisc plus	ES/SAF/FAS	DISCUS HERNIATION Hwk 6/7	16SEP2014	19DEC2014	06MAR2017 /12:22	Yes	L4 and L5 Right		No	No	No
	NDisc plus	ES/SAF/FAS	Recidive discus herniation L4/L5 right	16SEP2014	19DEC2014	24MAY2018	Yes	L4 and L5 Right		No	No	No
	NDisc plus	ES/SAF/FAS	discus herniation L3/L4	16SEP2014	19DEC2014	24MAY2018	Yes	L4 and L5 Right		No	No	No
01-0126	NDisc basic	ES/SAF/FAS	Reherniation	08OCT2014	08JAN2015	04MAR2015	Yes	L4 and L5 Left		Yes	No	Yes
01-0127	NDisc plus	ES/SAF/FAS	Reherniation/Discus prolaps L5/S1 right side	20OCT2014	09JAN2015	14FEB2018	No	L5 and S1 Right		Yes	No	
01-0131	NDisc plus	ES/SAF/FAS	cervical disc protrusion C5/6	01DEC2014	19FEB2015	--NOV2018	No	L4 and L5 Right		No	No	No

Listing 16.2.3.2: Subjects with adverse event 'intervertebral disc protrusion' (preferred term) - all enrolled subjects

Site/ Subject ID	Treat- ment Group	Analysis Set	Reported Term	Date of		AE Start date/time	Serious -ness	Location (Screening)		Outcome MRI 'Dorsal disc extrusion' Visit 3a		
				Sequest- rectomy	Implant- ation			herniated disc	adjacent disc	Central	Cranial not trt.	Cranial add.trt. Caudal
01-0133	NDisc plus	ES/SAF	REHERNIATION	16DEC2014		29DEC2014	Yes	L4 and L5 Left				
01-0136	NDisc basic	ES/SAF/FAS	Reherniation L4/L5 right	23FEB2015	02JUN2015	21OCT2015	No	L4 and L5 Right		No	No	No
01-0139	NDisc plus	ES/SAF/FAS	REHERNIATION L5/S1 RIGHT	10MAR2015	03JUN2015	11DEC2016	No	L5 and S1 Right		Yes	No	
	NDisc plus	ES/SAF/FAS	Reherniation L5/S1 right	10MAR2015	03JUN2015	23JAN2017	Yes	L5 and S1 Right		Yes	No	
01-0144	NDisc basic	ES/SAF/FAS	disc reherniation L5/S1	24JUN2015	22SEP2015	--NOV2018	No	L5 and S1 Left		Yes	No	
02-0201	NDisc plus	ES/SAF/FAS	Rezidiv prolaps L4/5 right side	13FEB2013	07MAY2013	28DEC2015 /15:30	Yes	L4 and L5 Left	L5 and S1 UNK	Yes	No	No
02-0203	NDisc basic	ES/SAF/FAS	Disc herniation L3/L4 right	28MAR2013	26JUN2013	05MAR2014 /10:30	No	L4 and L5 Left	L3 and L4 Left	Yes	No	No
02-0208	NDisc plus	ES/SAF/FAS	Disc rehernation L5/S1	12SEP2013	10DEC2013	16DEC2013	Yes	L5 and S1 Left	L4 and L5 Left/Right	No	No	
	NDisc plus	ES/SAF/FAS	Suspected Rezidivprolaps L5/S1 in MRI	12SEP2013	10DEC2013	01APR2014 /08:15	Yes	L5 and S1 Left	L4 and L5 Left/Right	No	No	
	NDisc plus	ES/SAF/FAS	Rezidiv L5/S1 Prolaps MRI 04.09.2015	12SEP2013	10DEC2013	01SEP2015	No	L5 and S1 Left	L4 and L5 Left/Right	No	No	
	NDisc plus	ES/SAF/FAS	Rezidiv prolaps L5/S1 left	12SEP2013	10DEC2013	21SEP2015 /10:00	Yes	L5 and S1 Left	L4 and L5 Left/Right	No	No	
	NDisc plus	ES/SAF/FAS	suspected Rezidivprolaps L5/S1 in MRI	12SEP2013	10DEC2013	25MAR2014	No	L5 and S1 Left	L4 and L5 Left/Right	No	No	
02-0211	NDisc basic	ES/SAF	Rezidiv L5/S1	11DEC2014		04MAR2015	No	L5 and S1 Right		Yes	No	

Listing 16.2.3.2: Subjects with adverse event 'intervertebral disc protrusion' (preferred term) - all enrolled subjects

Site/ Subject ID	Treat- ment Group	Analysis Set	Reported Term	Date of		AE Start date/time	Serious -ness	Location (Screening)		Outcome MRI 'Dorsal disc extrusion' Visit 3a		
				Sequest- rectomy	Implant- ation			herniated disc	adjacent disc	Central	Cranial not trt.	Cranial add.trt. Caudal
02-0214	NDisc plus	ES/SAF/FAS	Recurrent disc herniation	25FEB2015	28MAY2015	15OCT2020	Yes	L4 and L5 Right		Yes	No	No
02-0216	NDisc plus	ES/SAF/FAS	Rezidiv intervertebral disk L5/S1 right	28APR2015	23JUL2015	21AUG2015	No	L5 and S1 Right	L4 and L5 Right	Yes	No	
02-0221	NDisc plus	ES/SAF	Rezidiv L4/L5 left	01SEP2015		10DEC2015	No	L4 and L5 Left		Yes	No	No
06-0610	NDisc plus	ES/SAF/FAS	Rezidiv disc prolaps L5/S1	25JUN2015	08SEP2015	18JAN2016 /09:00	Yes	L5 and S1 Left	L4 and L5 Left	Yes		Yes
06-0614	NDisc plus	ES/SAF/FAS	Rezidiv disc prolaps L5/S1 right side	18AUG2015	18NOV2015	10MAR2016 /10:00	Yes	L5 and S1 Right	L4 and L5 Right	Yes		No
	NDisc plus	ES/SAF/FAS	Rezidiv sequester L5/S1 right side	18AUG2015	18NOV2015	10AUG2016 /10:00	Yes	L5 and S1 Right	L4 and L5 Right	Yes		No
06-0617	NDisc plus	ES/SAF	Recurrence of disc herniation L4/5 right side	22DEC2015		08MAR2016 /07:00	No	L4 and L5 Right	L3 and L4	Yes	No	No
08-0805	NDisc basic	ES/SAF/FAS	Recurrence disc herniation L2/L3	25JUN2015	22SEP2015	28JUL2016 /08:00	Yes	L2 and L3 Right		No	No	No
09-0905	NDisc plus	ES/SAF/FAS	Recurrent lumbar disherniation L4/L5 righ	19MAR2015	25JUN2015	01SEP2018	No	L4 and L5 Right		No	No	No
	NDisc plus	ES/SAF/FAS	Recurrent lumbar disc herniation L4/L5 re	19MAR2015	25JUN2015	10MAR2019	Yes	L4 and L5 Right		No	No	No
09-0915	NDisc basic	ES/SAF/FAS	Rezidiv Prolaps L4 L5 re	06JAN2016	24MAR2016	14JUL2020	No	L4 and L5 Right		Yes	No	No

Listing 16.2.3.2: Subjects with adverse event 'intervertebral disc protrusion' (preferred term) - all enrolled subjects

Site/ Subject ID	Treat- ment Group	Analysis Set	Reported Term	Date of		AE Start date/time	Serious -ness	Location (Screening)		Outcome MRI 'Dorsal disc extrusion' Visit 3a		
				Sequest- rectomy	Implant- ation			herniated disc	adjacent disc	Central	Cranial not trt.	Cranial add.trt. Caudal
11-1101	NDisc plus	ES/SAF/FAS	Relapse L5/S1	13JAN2015	31MAR2015	27SEP2017	Yes	L5 and S1 Left	L4 and L5 Left/Right	Yes		No
	NDisc plus	ES/SAF/FAS	Relapse L5/S1 left	13JAN2015	31MAR2015	30JUL2019 /10:02	Yes	L5 and S1 Left	L4 and L5 Left/Right	Yes		No
11-1103	SC	ES/SAF/FAS	Relapse L5/S1	03AUG2015		03JAN2018 /18:12	Yes	L5 and S1 Left				
12-1201	NDisc plus	ES/SAF/FAS	prolaps lumbar disc LWK5/SWK1	07SEP2015	01DEC2015	22NOV2016	No	L5 and S1 Right		Yes	No	

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
01/0103	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	17OCT2012	132/85	62.0	172.0	82.0
	ND basic	ES/SAF/FAS	VISIT 3A	14JAN2013	207/106	67.0	172.0	82.0
	ND basic	ES/SAF/FAS	VISIT 4	20FEB2013	145/95	73.0	172.0	82.0
	ND basic	ES/SAF/FAS	VISIT 5	17APR2013	147/97	68.0	172.0	87.0
	ND basic	ES/SAF/FAS	VISIT 6	18JUL2013	140/90	68.0	174.0	83.0
	ND basic	ES/SAF/FAS	VISIT 7	08JAN2014	182/114	76.0	173.0	85.0
	ND basic	ES/SAF/FAS	VISIT 8	16FEB2015	138/87	71.0	174.0	86.0
	ND basic	ES/SAF/FAS	VISIT 11	17JAN2018	174/102	75.0	174.0	90.0
01/0104	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	23OCT2012	142/97	80.0	180.0	78.0
	ND basic	ES/SAF/FAS	VISIT 3A	21JAN2013	143/82	73.0	180.0	78.0
	ND basic	ES/SAF/FAS	VISIT 4	27FEB2013	125/80	72.0	180.0	78.0
	ND basic	ES/SAF/FAS	VISIT 5	26APR2013	120/75	78.0	180.0	78.0
	ND basic	ES/SAF/FAS	VISIT 6	31JUL2013	120/80	60.0	180.0	78.0
	ND basic	ES/SAF/FAS	VISIT 7	15JAN2014	139/80	66.0	181.0	78.0
	ND basic	ES/SAF/FAS	VISIT 8	23JUN2015	129/80	72.0	180.0	73.0
	ND basic	ES/SAF/FAS	VISIT 11	24JAN2018	149/84	73.0	181.0	74.0
01/0106	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	27NOV2012	129/92	64.0	180.0	84.0
	ND plus	ES/SAF/FAS	VISIT 3A	18FEB2013	146/88	59.0	180.0	85.0
	ND plus	ES/SAF/FAS	VISIT 4	03APR2013	140/87	80.0	180.0	87.0
	ND plus	ES/SAF/FAS	VISIT 5	22MAY2013	135/95	68.0	180.0	87.0
	ND plus	ES/SAF/FAS	VISIT 6	21AUG2013	144/102	79.0	180.0	85.0
	ND plus	ES/SAF/FAS	VISIT 7	19FEB2014	156/99	72.0	180.0	86.0
	ND plus	ES/SAF/FAS	VISIT 8	18FEB2015	135/90	68.0	180.0	87.0
	ND plus	ES/SAF/FAS	VISIT 11	14FEB2018	164/97	74.0	180.0	95.0
01/0107	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	08JAN2013	140/80	76.0	170.0	75.0
	ND plus	ES/SAF/FAS	VISIT 3A	08APR2013	142/84	73.0	170.0	78.0
	ND plus	ES/SAF/FAS	VISIT 4	15MAY2013	140/90	75.0	170.0	78.0
	ND plus	ES/SAF/FAS	VISIT 5	03JUL2013	135/85	69.0	170.0	76.0
	ND plus	ES/SAF/FAS	VISIT 6	25SEP2013	154/98	83.0	170.0	73.0
	ND plus	ES/SAF/FAS	VISIT 7	26MAR2014	164/94	73.0	170.0	77.0
	ND plus	ES/SAF/FAS	VISIT 8	08APR2015	146/89	91.0	170.0	72.0
	ND plus	ES/SAF/FAS	VISIT 11	11APR2018	158/85	89.0	170.0	72.0
01/0108	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	09JAN2013	142/81	64.0	195.0	95.0
	ND plus	ES/SAF/FAS	VISIT 3A	15APR2013	138/78	65.0	195.0	95.0
	ND plus	ES/SAF/FAS	VISIT 4	29MAY2013	146/85	68.0	195.0	95.0
	ND plus	ES/SAF/FAS	VISIT 5	11JUL2013	140/90	65.0	195.0	95.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
01/0108	ND plus	ES/SAF/FAS	VISIT 6	01OCT2013	146/93	78.0	195.0	97.0
	ND plus	ES/SAF/FAS	VISIT 7	02APR2014	147/90	71.0	195.0	95.0
	ND plus	ES/SAF/FAS	VISIT 8	16APR2015	155/93	73.0	195.0	100.0
	ND plus	ES/SAF/FAS	VISIT 11	21MAR2018	163/95	75.0	195.0	100.0
01/0110	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	23JAN2013	156/80	63.0	160.0	58.0
	ND basic	ES/SAF/FAS	VISIT 3A	22APR2013	114/65	52.0	160.0	64.0
	ND basic	ES/SAF/FAS	VISIT 4	05JUN2013	140/80	60.0	160.0	65.0
	ND basic	ES/SAF/FAS	VISIT 5	31JUL2013	115/85	60.0	160.0	60.0
	ND basic	ES/SAF/FAS	VISIT 6	15OCT2013	139/98	65.0	160.0	63.0
	ND basic	ES/SAF/FAS	VISIT 7	09APR2014	146/90	65.0	160.0	62.0
	ND basic	ES/SAF/FAS	VISIT 8	22APR2015	137/87	66.0	160.0	61.0
	ND basic	ES/SAF/FAS	VISIT 11	28MAR2018	135/85	70.0	160.0	58.0
01/0111	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	11MAR2013	131/87	70.0	187.0	93.0
	ND plus	ES/SAF/FAS	VISIT 3A	10JUN2013	147/98	68.0	187.0	93.0
	ND plus	ES/SAF/FAS	VISIT 4	25JUL2013	120/90	60.0	187.0	93.0
	ND plus	ES/SAF/FAS	VISIT 5	04SEP2013	125/80	60.0	187.0	93.0
	ND plus	ES/SAF/FAS	VISIT 6	18DEC2013	149/101	64.0	187.0	93.0
	ND plus	ES/SAF/FAS	VISIT 7	04JUN2014	130/100	82.0	187.0	93.0
	ND plus	ES/SAF/FAS	VISIT 8	10JUN2015	143/89	75.0	187.0	93.0
	ND plus	ES/SAF/FAS	VISIT 11	30MAY2018	148/103	86.0	187.0	95.0
01/0112	ND basic	ES/SAF	BASELINE (VISIT 2A)	26MAR2013	134/102	79.0	157.0	70.0
	ND basic	ES/SAF	UNSCHEDULED	02APR2013	133/90	74.0	157.0	70.0
	ND basic	ES/SAF	VISIT 11	08JUL2013	125/75	60.0	157.0	70.0
01/0113	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	22MAY2013	144/80	56.0	180.0	85.0
	ND basic	ES/SAF/FAS	VISIT 3A	05AUG2013	118/82	66.0	180.0	86.0
	ND basic	ES/SAF/FAS	VISIT 4	10SEP2013	125/80	66.0	180.0	85.0
	ND basic	ES/SAF/FAS	VISIT 5	06NOV2013	123/83	60.0	180.0	85.0
	ND basic	ES/SAF/FAS	VISIT 6	28JAN2014	138/86	61.0	180.0	85.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	11JUL2014	115/78	60.0	180.0	85.0
	ND basic	ES/SAF/FAS	VISIT 7	30JUL2014	150/88	73.0	180.0	85.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	04AUG2014	130/80	51.0	180.0	85.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	03SEP2014	125/89	93.0	180.0	85.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	02OCT2014	138/85	67.0	180.0	85.0
	ND basic	ES/SAF/FAS	VISIT 8	22JUL2015	122/86	59.0	180.0	85.0
	ND basic	ES/SAF/FAS	VISIT 11	17OCT2018	141/84	84.0	180.0	88.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
01/0114	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	10JUN2013	102/76	62.0	176.0	67.0
	ND basic	ES/SAF/FAS	VISIT 3A	10SEP2013	115/80	56.0	176.0	67.0
	ND basic	ES/SAF/FAS	VISIT 4	16OCT2013	115/80	52.0	176.0	67.0
	ND basic	ES/SAF/FAS	VISIT 5	10DEC2013	121/81	68.0	176.0	67.0
	ND basic	ES/SAF/FAS	VISIT 6	12MAR2014	122/81	58.0	176.0	70.0
	ND basic	ES/SAF/FAS	VISIT 7	10SEP2014	139/78	53.0	176.0	69.0
	ND basic	ES/SAF/FAS	VISIT 8	09SEP2015	116/81	61.0	176.0	70.0
	ND basic	ES/SAF/FAS	VISIT 11	05SEP2018	122/89	61.0	176.0	74.0
01/0115	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	11JUN2013	135/92	64.0	180.0	75.0
	ND plus	ES/SAF/FAS	VISIT 3A	16SEP2013	132/87	83.0	180.0	75.0
	ND plus	ES/SAF/FAS	VISIT 4	30OCT2013	134/87	64.0	180.0	75.0
	ND plus	ES/SAF/FAS	VISIT 5	12DEC2013	137/99	82.0	180.0	75.0
	ND plus	ES/SAF/FAS	VISIT 6	11MAR2014	141/105	72.0	180.0	75.0
	ND plus	ES/SAF/FAS	VISIT 7	25SEP2014	140/87	70.0	180.0	75.0
	ND plus	ES/SAF/FAS	VISIT 8	16SEP2015	139/98	99.0	180.0	75.0
	ND plus	ES/SAF/FAS	VISIT 11	10OCT2018	148/95	83.0	180.0	75.0
01/0116	ND basic	ES/SAF	BASELINE (VISIT 2A)	17JUN2013	138/74	55.0	184.0	67.0
01/0118	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	09JUL2013	134/86	67.0	183.0	85.0
	ND plus	ES/SAF/FAS	VISIT 3A	07OCT2013	154/74	82.0	183.0	85.0
	ND plus	ES/SAF/FAS	VISIT 4	20NOV2013	145/91	83.0	183.0	85.0
	ND plus	ES/SAF/FAS	VISIT 5	07JAN2014	168/102	73.0	183.0	85.0
	ND plus	ES/SAF/FAS	VISIT 6	25MAR2014	153/103	80.0	183.0	85.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	28MAY2014	145/91	83.0	183.0	85.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	09JUL2014	142/90	77.0	183.0	85.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	20AUG2014	-/-	-	183.0	85.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	18SEP2014	-/-	-	183.0	85.0
	ND plus	ES/SAF/FAS	VISIT 7	08OCT2014	158/89	62.0	183.0	85.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	22OCT2014	-/-	-	183.0	85.0
	ND plus	ES/SAF/FAS	VISIT 8	07OCT2015	125/87	64.0	183.0	80.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	15JUN2016	-/-	-	183.0	78.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	16JAN2018	110/66	62.0	-	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	01FEB2018	122/76	77.0	183.0	85.0
	ND plus	ES/SAF/FAS	VISIT 11	03OCT2018	145/85	84.0	183.0	85.0
01/0119	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	22JUL2013	120/80	60.0	176.0	83.0
	ND basic	ES/SAF/FAS	VISIT 3A	14OCT2013	146/99	89.0	176.0	82.0
	ND basic	ES/SAF/FAS	VISIT 4	19NOV2013	136/86	92.0	176.0	83.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
01/0119	ND basic	ES/SAF/FAS	VISIT 5	14JAN2014	130/95	105.0	178.0	83.0
	ND basic	ES/SAF/FAS	VISIT 6	03APR2014	142/88	87.0	176.0	83.0
	ND basic	ES/SAF/FAS	VISIT 7	15OCT2014	148/89	98.0	176.0	83.0
	ND basic	ES/SAF/FAS	VISIT 8	14OCT2015	140/94	77.0	176.0	87.0
	ND basic	ES/SAF/FAS	VISIT 11	10OCT2018	143/89	85.0	176.0	84.0
01/0121	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	14OCT2013	149/75	65.0	189.0	89.0
	ND plus	ES/SAF/FAS	VISIT 3A	13JAN2014	125/80	72.0	190.0	90.0
	ND plus	ES/SAF/FAS	VISIT 4	18FEB2014	141/83	77.0	189.0	90.0
	ND plus	ES/SAF/FAS	VISIT 5	08APR2014	153/82	87.0	189.0	90.0
	ND plus	ES/SAF/FAS	VISIT 6	14JUL2014	141/80	99.0	190.0	90.0
	ND plus	ES/SAF/FAS	VISIT 7	21JAN2015	141/85	62.0	189.0	89.0
	ND plus	ES/SAF/FAS	VISIT 8	13JAN2016	143/86	64.0	189.0	92.0
01/0122	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	25SEP2013	153/102	75.0	173.0	68.0
	ND plus	ES/SAF/FAS	VISIT 3A	16DEC2013	142/93	92.0	175.0	68.0
	ND plus	ES/SAF/FAS	VISIT 4	29JAN2014	134/81	76.0	175.0	70.0
	ND plus	ES/SAF/FAS	VISIT 5	18MAR2014	137/99	86.0	175.0	69.0
	ND plus	ES/SAF/FAS	VISIT 6	11JUN2014	142/90	80.0	175.0	68.0
	ND plus	ES/SAF/FAS	VISIT 7	17DEC2014	160/102	89.0	175.0	71.0
	ND plus	ES/SAF/FAS	VISIT 8	16DEC2015	130/90	89.0	175.0	71.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	15JUN2016	-/-	-	175.0	74.0
	ND plus	ES/SAF/FAS	VISIT 11	19DEC2018	146/104	90.0	175.0	76.0
01/0123	ND plus	ES/SAF/FAS	VISIT 1	15SEP2014	144/94	72.0	174.0	88.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	15SEP2014	144/94	72.0	174.0	88.0
	ND plus	ES/SAF/FAS	VISIT 3A	18DEC2014	138/88	66.0	174.0	89.0
	ND plus	ES/SAF/FAS	VISIT 4	28JAN2015	129/86	59.0	173.0	90.0
	ND plus	ES/SAF/FAS	VISIT 5	20MAR2015	126/87	64.0	173.0	87.0
	ND plus	ES/SAF/FAS	VISIT 6	02JUL2015	133/83	70.0	173.0	87.0
	ND plus	ES/SAF/FAS	VISIT 7	17DEC2015	134/84	60.0	173.0	90.0
	ND plus	ES/SAF/FAS	VISIT 8	07DEC2016	158/98	74.0	173.0	92.0
01/0124	ND plus	ES/SAF	VISIT 1	01OCT2014	150/104	101.0	175.0	72.0
	ND plus	ES/SAF	BASELINE (VISIT 2A)	05NOV2014	170/90	100.0	175.0	72.0
01/0125	SC	ES/SAF/FAS	VISIT 1	06OCT2014	140/89	85.0	179.0	65.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	06OCT2014	140/89	85.0	179.0	65.0
	SC	ES/SAF/FAS	VISIT 4	19NOV2014	123/87	83.0	179.0	65.0
	SC	ES/SAF/FAS	VISIT 5	07JAN2015	134/94	79.0	179.0	65.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
01/0125	SC	ES/SAF/FAS	VISIT 6	25MAR2015	134/82	84.0	179.0	65.0
	SC	ES/SAF/FAS	VISIT 7	30SEP2015	150/94	81.0	179.0	65.0
	SC	ES/SAF/FAS	VISIT 8	28SEP2016	116/86	75.0	179.0	65.0
	SC	ES/SAF/FAS	UNSCHEDULED	10JAN2018	134/92	75.0	179.0	65.0
	SC	ES/SAF/FAS	VISIT 11	02OCT2019	130/75	68.0	179.0	65.0
01/0126	ND basic	ES/SAF/FAS	VISIT 1	06OCT2014	100/65	84.0	167.0	60.0
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	07OCT2014	100/70	80.0	167.0	60.0
	ND basic	ES/SAF/FAS	VISIT 3A	07JAN2015	144/94	44.0	167.0	59.0
	ND basic	ES/SAF/FAS	VISIT 4	16FEB2015	118/64	80.0	167.0	62.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	04MAR2015	119/76	58.0	167.0	62.0
	ND basic	ES/SAF/FAS	VISIT 5	08APR2015	112/64	66.0	168.0	60.0
	ND basic	ES/SAF/FAS	VISIT 6	30JUN2015	143/75	41.0	167.0	60.0
	ND basic	ES/SAF/FAS	VISIT 7	12JAN2016	124/69	43.0	167.0	58.0
	ND basic	ES/SAF/FAS	VISIT 8	11JAN2017	122/68	39.0	167.0	62.0
	ND basic	ES/SAF/FAS	VISIT 11	11DEC2019	137/74	68.0	167.0	62.0
01/0127	ND plus	ES/SAF/FAS	VISIT 1	17OCT2014	126/70	50.0	178.0	74.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	19OCT2014	126/70	50.0	178.0	74.0
	ND plus	ES/SAF/FAS	VISIT 3A	08JAN2015	121/67	58.0	178.0	75.0
	ND plus	ES/SAF/FAS	VISIT 4	19FEB2015	130/78	56.0	178.0	75.0
	ND plus	ES/SAF/FAS	VISIT 5	08APR2015	130/79	62.0	178.0	76.0
	ND plus	ES/SAF/FAS	VISIT 6	01JUL2015	139/80	66.0	178.0	76.0
	ND plus	ES/SAF/FAS	VISIT 7	13JAN2016	138/86	74.0	178.0	75.0
	ND plus	ES/SAF/FAS	VISIT 8	11JAN2017	130/86	58.0	178.0	75.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	14FEB2018	145/90	61.0	178.0	75.0
	ND plus	ES/SAF/FAS	VISIT 11	18DEC2019	137/92	64.0	178.0	77.0
01/0128	ND plus	ES/SAF/FAS	VISIT 1	20OCT2014	148/98	84.0	184.0	86.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	21OCT2014	141/93	73.0	184.0	86.0
	ND plus	ES/SAF/FAS	VISIT 3A	12JAN2015	155/90	78.0	184.0	88.0
	ND plus	ES/SAF/FAS	VISIT 4	24FEB2015	134/92	71.0	185.0	89.0
	ND plus	ES/SAF/FAS	VISIT 5	14APR2015	152/89	70.0	185.0	88.0
	ND plus	ES/SAF/FAS	VISIT 6	14JUL2015	150/109	83.0	185.0	95.0
	ND plus	ES/SAF/FAS	VISIT 7	14JAN2016	155/93	66.0	185.0	97.0
	ND plus	ES/SAF/FAS	VISIT 8	25JAN2017	150/98	64.0	184.0	98.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	01MAR2019	-/-	-	184.0	-
	ND plus	ES/SAF/FAS	VISIT 11	18DEC2019	163/90	58.0	184.0	98.0
01/0129	SC	ES/SAF/FAS	VISIT 1	28OCT2014	142/86	59.0	175.0	86.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
01/0129	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	28OCT2014	134/94	58.0	175.0	86.0
	SC	ES/SAF/FAS	VISIT 4	10DEC2014	145/102	72.0	175.0	85.0
	SC	ES/SAF/FAS	VISIT 5	21JAN2015	146/97	72.0	175.0	85.0
	SC	ES/SAF/FAS	VISIT 6	14APR2015	143/98	75.0	175.0	86.0
	SC	ES/SAF/FAS	VISIT 7	21OCT2015	144/93	82.0	175.0	86.0
	SC	ES/SAF/FAS	VISIT 8	05OCT2016	141/102	72.0	175.0	87.0
	SC	ES/SAF/FAS	UNSCHEDULED	18MAR2019	152/101	65.0	175.0	89.0
	SC	ES/SAF/FAS	VISIT 11	02OCT2019	147/84	49.0	175.0	87.0
01/0130	ND basic	ES/SAF/FAS	VISIT 1	19NOV2014	174/109	70.0	168.0	80.0
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	19NOV2014	174/109	70.0	168.0	80.0
	ND basic	ES/SAF/FAS	VISIT 3A	03FEB2015	133/84	54.0	168.0	80.0
	ND basic	ES/SAF/FAS	VISIT 4	17MAR2015	130/90	73.0	168.0	80.0
	ND basic	ES/SAF/FAS	VISIT 5	27APR2015	136/92	67.0	168.0	80.0
	ND basic	ES/SAF/FAS	VISIT 6	29JUL2015	137/94	75.0	168.0	80.0
	ND basic	ES/SAF/FAS	VISIT 7	20JAN2016	138/98	64.0	168.0	80.0
	ND basic	ES/SAF/FAS	VISIT 8	01FEB2017	155/113	68.0	168.0	73.0
	ND basic	ES/SAF/FAS	VISIT 11	22JAN2020	147/78	64.0	168.0	73.0
01/0131	ND plus	ES/SAF/FAS	VISIT 1	28NOV2014	168/110	86.0	177.0	67.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	30NOV2014	165/100	86.0	177.0	67.0
	ND plus	ES/SAF/FAS	VISIT 3A	18FEB2015	150/94	71.0	177.0	67.0
	ND plus	ES/SAF/FAS	VISIT 4	09APR2015	140/95	77.0	177.0	68.0
	ND plus	ES/SAF/FAS	VISIT 5	27MAY2015	129/92	82.0	177.0	68.0
	ND plus	ES/SAF/FAS	VISIT 6	18AUG2015	147/98	70.0	176.0	70.0
	ND plus	ES/SAF/FAS	VISIT 7	18FEB2016	164/99	69.0	176.0	73.0
	ND plus	ES/SAF/FAS	VISIT 8	15MAR2017	147/88	79.0	176.0	74.0
	ND plus	ES/SAF/FAS	VISIT 11	29JAN2020	135/88	76.0	176.0	79.0
01/0132	SC	ES/SAF/FAS	VISIT 1	01DEC2014	122/82	49.0	191.0	82.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	01DEC2014	122/82	49.0	191.0	82.0
	SC	ES/SAF/FAS	VISIT 4	13JAN2015	122/74	62.0	191.0	78.0
	SC	ES/SAF/FAS	VISIT 5	18MAR2015	130/88	81.0	191.0	82.0
	SC	ES/SAF/FAS	VISIT 6	20MAY2015	130/78	73.0	199.0	82.0
	SC	ES/SAF/FAS	VISIT 7	25NOV2015	128/79	71.0	191.0	84.0
	SC	ES/SAF/FAS	VISIT 8	23NOV2016	128/79	70.0	191.0	84.0
	SC	ES/SAF/FAS	VISIT 11	20NOV2019	134/85	72.0	191.0	85.0
01/0133	ND plus	ES/SAF	VISIT 1	15DEC2014	170/100	61.0	168.0	76.0
	ND plus	ES/SAF	BASELINE (VISIT 2A)	15DEC2014	170/100	61.0	168.0	76.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
01/0133	ND plus	ES/SAF	UNSCHEDULED	29DEC2014	140/95	60.0	168.0	76.0
01/0134	ND basic	ES/SAF	VISIT 1	16DEC2014	116/82	88.0	175.0	72.0
	ND basic	ES/SAF	BASELINE (VISIT 2A)	16DEC2014	116/82	88.0	175.0	72.0
	ND basic	ES/SAF	UNSCHEDULED	15JAN2015	-/-	-	175.0	72.0
01/0135	ND plus	ES/SAF/FAS	VISIT 1	14JAN2015	153/98	52.0	163.0	54.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	14JAN2015	153/98	52.0	163.0	54.0
	ND plus	ES/SAF/FAS	VISIT 3A	07APR2015	128/98	60.0	163.0	55.0
	ND plus	ES/SAF/FAS	VISIT 4	26MAY2015	138/94	57.0	163.0	54.0
	ND plus	ES/SAF/FAS	VISIT 5	07JUL2015	151/91	52.0	163.0	54.0
	ND plus	ES/SAF/FAS	VISIT 6	06OCT2015	145/90	59.0	163.0	53.0
	ND plus	ES/SAF/FAS	VISIT 7	06APR2016	133/91	56.0	164.0	54.0
	ND plus	ES/SAF/FAS	VISIT 8	03MAY2017	152/99	50.0	163.0	55.0
	ND plus	ES/SAF/FAS	VISIT 11	27MAY2020	135/92	64.0	163.0	56.0
01/0136	ND basic	ES/SAF/FAS	VISIT 1	20FEB2015	123/109	109.0	189.0	105.0
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	22FEB2015	130/60	72.0	189.0	105.0
	ND basic	ES/SAF/FAS	VISIT 3A	02JUN2015	120/68	58.0	188.0	105.0
	ND basic	ES/SAF/FAS	VISIT 4	15JUL2015	136/96	108.0	189.0	105.0
	ND basic	ES/SAF/FAS	VISIT 5	26AUG2015	110/83	82.0	189.0	105.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	21OCT2015	-/-	-	189.0	105.0
	ND basic	ES/SAF/FAS	VISIT 6	24NOV2015	118/83	87.0	189.0	104.0
	ND basic	ES/SAF/FAS	VISIT 7	25MAY2016	127/86	90.0	189.0	104.0
	ND basic	ES/SAF/FAS	VISIT 8	06JUN2017	140/96	83.0	189.0	108.0
	ND basic	ES/SAF/FAS	VISIT 11	10JUN2020	115/72	92.0	189.0	107.0
01/0137	ND plus	ES/SAF/FAS	VISIT 1	25FEB2015	116/83	83.0	163.0	53.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	25FEB2015	116/83	83.0	163.0	53.0
	ND plus	ES/SAF/FAS	VISIT 3A	01JUN2015	150/99	70.0	163.0	55.0
	ND plus	ES/SAF/FAS	VISIT 4	16JUL2015	134/84	81.0	163.0	55.0
	ND plus	ES/SAF/FAS	VISIT 5	25AUG2015	126/89	79.0	163.0	55.0
	ND plus	ES/SAF/FAS	VISIT 6	18NOV2015	128/86	76.0	162.0	55.0
	ND plus	ES/SAF/FAS	VISIT 7	01JUN2016	137/94	67.0	163.0	55.0
	ND plus	ES/SAF/FAS	VISIT 8	07JUN2017	143/106	81.0	162.0	56.0
	ND plus	ES/SAF/FAS	VISIT 11	24JUN2020	136/100	76.0	162.0	58.0
01/0138	SC	ES/SAF/FAS	VISIT 1	05MAR2015	154/96	85.0	180.0	82.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	08MAR2015	135/86	75.0	180.0	82.0
	SC	ES/SAF/FAS	VISIT 4	23APR2015	146/96	77.0	180.0	83.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
01/0138	SC	ES/SAF/FAS	VISIT 5	05JUN2015	129/94	93.0	180.0	84.0
	SC	ES/SAF/FAS	VISIT 6	15SEP2015	153/98	83.0	180.0	86.0
	SC	ES/SAF/FAS	VISIT 7	24FEB2016	142/105	107.0	180.0	89.0
	SC	ES/SAF/FAS	VISIT 8	08FEB2017	140/85	71.0	180.0	90.0
	SC	ES/SAF/FAS	VISIT 11	12FEB2020	137/79	68.0	180.0	91.0
01/0139	ND plus	ES/SAF/FAS	VISIT 1	09MAR2015	159/104	76.0	186.0	100.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	09MAR2015	159/104	76.0	186.0	100.0
	ND plus	ES/SAF/FAS	VISIT 3A	02JUN2015	168/102	89.0	186.0	100.0
	ND plus	ES/SAF/FAS	VISIT 4	14JUL2015	161/113	80.0	186.0	100.0
	ND plus	ES/SAF/FAS	VISIT 5	26AUG2015	175/113	83.0	186.0	100.0
	ND plus	ES/SAF/FAS	VISIT 6	02DEC2015	161/107	90.0	186.0	100.0
	ND plus	ES/SAF/FAS	VISIT 7	15JUN2016	169/115	83.0	186.0	100.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	21DEC2016	-/-	-	186.0	100.0
01/0140	ND plus	ES/SAF/FAS	VISIT 8	07JUN2017	160/103	83.0	186.0	110.0
	ND basic	ES/SAF/FAS	VISIT 1	11MAY2015	151/100	81.0	176.0	74.0
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	12MAY2015	126/90	71.0	176.0	74.0
	ND basic	ES/SAF/FAS	VISIT 3A	10AUG2015	147/93	77.0	176.0	74.0
	ND basic	ES/SAF/FAS	VISIT 4	22SEP2015	146/109	81.0	176.0	75.0
	ND basic	ES/SAF/FAS	VISIT 5	04NOV2015	140/93	82.0	176.0	77.0
	ND basic	ES/SAF/FAS	VISIT 6	08FEB2016	133/86	72.0	176.0	72.0
	ND basic	ES/SAF/FAS	VISIT 7	27JUL2016	153/91	80.0	176.0	72.0
01/0141	ND basic	ES/SAF/FAS	VISIT 8	26JUL2017	150/95	63.0	176.0	77.0
	ND basic	ES/SAF/FAS	VISIT 11	19AUG2020	140/90	86.0	176.0	75.0
	SC	ES/SAF/FAS	VISIT 1	21MAY2015	136/83	71.0	170.0	73.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	26MAY2015	136/85	85.0	170.0	73.0
	SC	ES/SAF/FAS	VISIT 4	13JUL2015	126/100	95.0	170.0	70.0
	SC	ES/SAF/FAS	VISIT 5	02SEP2015	139/79	63.0	170.0	70.0
	SC	ES/SAF/FAS	VISIT 6	11NOV2015	132/82	66.0	170.0	70.0
	SC	ES/SAF/FAS	VISIT 7	18MAY2016	127/75	58.0	170.0	68.0
01/0142	SC	ES/SAF/FAS	VISIT 8	10MAY2017	131/89	89.0	170.0	70.0
	SC	ES/SAF/FAS	VISIT 11	24JUN2020	131/92	68.0	170.0	78.0
	SC	ES/SAF/FAS	UNSCHEDULED	03MAR2021	120/70	76.0	170.0	72.0
	ND plus	ES/SAF/FAS	VISIT 1	26MAY2015	122/90	65.0	165.0	58.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	27MAY2015	116/81	69.0	165.0	58.0
	ND plus	ES/SAF/FAS	VISIT 3A	24AUG2015	107/70	61.0	165.0	59.0
	ND plus	ES/SAF/FAS	VISIT 4	05OCT2015	106/77	67.0	165.0	58.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
01/0142	ND plus	ES/SAF/FAS	VISIT 5	25NOV2015	120/73	63.0	165.0	57.0
	ND plus	ES/SAF/FAS	VISIT 6	02MAR2016	110/69	79.0	165.0	57.0
	ND plus	ES/SAF/FAS	VISIT 7	31AUG2016	102/63	58.0	165.0	65.0
	ND plus	ES/SAF/FAS	VISIT 8	30AUG2017	118/71	62.0	165.0	57.0
	ND plus	ES/SAF/FAS	VISIT 11	05AUG2020	100/60	60.0	165.0	59.0
01/0143	ND plus	ES/SAF/FAS	VISIT 1	15JUN2015	-/-	-	192.0	92.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	16JUN2015	130/85	70.0	192.0	92.0
	ND plus	ES/SAF/FAS	VISIT 3A	22SEP2015	110/70	68.0	192.0	92.0
	ND plus	ES/SAF/FAS	VISIT 4	02NOV2015	127/86	71.0	192.0	92.0
	ND plus	ES/SAF/FAS	VISIT 5	16DEC2015	130/89	94.0	192.0	92.0
	ND plus	ES/SAF/FAS	VISIT 6	09MAR2016	135/85	96.0	192.0	92.0
	ND plus	ES/SAF/FAS	VISIT 7	07SEP2016	123/89	98.0	193.0	95.0
	ND plus	ES/SAF/FAS	VISIT 8	23AUG2017	130/86	82.0	192.0	94.0
	ND plus	ES/SAF/FAS	VISIT 11	16SEP2020	110/80	60.0	192.0	98.0
01/0144	ND basic	ES/SAF/FAS	VISIT 1	22JUN2015	154/93	95.0	180.0	78.0
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	23JUN2015	154/93	95.0	180.0	78.0
	ND basic	ES/SAF/FAS	VISIT 3A	22SEP2015	118/71	49.0	180.0	78.0
	ND basic	ES/SAF/FAS	VISIT 4	03NOV2015	122/85	65.0	180.0	80.0
	ND basic	ES/SAF/FAS	VISIT 5	17DEC2015	126/85	83.0	180.0	80.0
	ND basic	ES/SAF/FAS	VISIT 6	30MAR2016	136/80	78.0	180.0	80.0
	ND basic	ES/SAF/FAS	VISIT 7	21SEP2016	139/84	72.0	180.0	80.0
	ND basic	ES/SAF/FAS	VISIT 8	30AUG2017	148/72	71.0	180.0	81.0
	ND basic	ES/SAF/FAS	VISIT 11	09SEP2020	144/98	84.0	180.0	80.0
01/0145	ND plus	ES/SAF/FAS	VISIT 1	14JUL2015	134/89	57.0	172.0	75.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	15JUL2015	130/82	73.0	172.0	75.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	14SEP2015	158/104	106.0	172.0	75.0
	ND plus	ES/SAF/FAS	VISIT 3A	05OCT2015	141/107	87.0	172.0	75.0
	ND plus	ES/SAF/FAS	VISIT 4	19NOV2015	138/96	74.0	172.0	75.0
	ND plus	ES/SAF/FAS	VISIT 5	05JAN2016	161/104	77.0	172.0	70.0
	ND plus	ES/SAF/FAS	VISIT 6	05APR2016	131/94	71.0	172.0	70.0
	ND plus	ES/SAF/FAS	VISIT 7	05OCT2016	133/90	88.0	172.0	70.0
	ND plus	ES/SAF/FAS	VISIT 8	20SEP2017	166/110	73.0	-	-
	ND plus	ES/SAF/FAS	VISIT 11	30SEP2020	126/84	86.0	172.0	75.0
01/0146	SC	ES/SAF/FAS	VISIT 1	15JUL2015	142/102	75.0	173.0	85.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	15JUL2015	142/102	75.0	173.0	85.0
	SC	ES/SAF/FAS	VISIT 4	27AUG2015	113/84	84.0	174.0	81.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
01/0146	SC	ES/SAF/FAS	VISIT 5	13OCT2015	118/86	64.0	174.0	80.0
	SC	ES/SAF/FAS	VISIT 6	19JAN2016	143/96	71.0	173.0	80.0
	SC	ES/SAF/FAS	VISIT 7	06JUL2016	134/97	102.0	174.0	80.0
	SC	ES/SAF/FAS	VISIT 8	21JUN2017	148/102	79.0	174.0	81.0
	SC	ES/SAF/FAS	VISIT 11	26AUG2020	106/82	64.0	173.0	90.0
01/0147	ND plus	ES/SAF/FAS	VISIT 1	19AUG2015	107/75	66.0	164.0	66.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	19AUG2015	107/75	66.0	164.0	66.0
	ND plus	ES/SAF/FAS	VISIT 3A	17NOV2015	117/67	76.0	164.0	69.0
	ND plus	ES/SAF/FAS	VISIT 4	05JAN2016	121/89	91.0	164.0	69.0
	ND plus	ES/SAF/FAS	VISIT 5	09FEB2016	114/86	86.0	164.0	67.0
	ND plus	ES/SAF/FAS	VISIT 6	11MAY2016	116/81	92.0	164.0	66.0
	ND plus	ES/SAF/FAS	VISIT 7	16NOV2016	130/95	80.0	164.0	67.0
	ND plus	ES/SAF/FAS	VISIT 8	15NOV2017	111/85	71.0	164.0	68.0
	ND plus	ES/SAF/FAS	VISIT 11	04NOV2020	130/85	68.0	164.0	68.0
01/0148	ND plus	ES/SAF/FAS	VISIT 1	21OCT2015	132/81	71.0	182.0	79.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	21OCT2015	132/81	71.0	182.0	79.0
	ND plus	ES/SAF/FAS	VISIT 3A	11JAN2016	134/88	87.0	182.0	79.0
	ND plus	ES/SAF/FAS	VISIT 4	24FEB2016	138/92	57.0	182.0	78.0
	ND plus	ES/SAF/FAS	VISIT 5	13APR2016	139/85	56.0	182.0	78.0
	ND plus	ES/SAF/FAS	VISIT 6	20JUN2016	141/83	53.0	182.0	78.0
	ND plus	ES/SAF/FAS	VISIT 7	14DEC2016	146/90	78.0	182.0	80.0
	ND plus	ES/SAF/FAS	VISIT 8	13DEC2017	132/82	57.0	182.0	77.0
	ND plus	ES/SAF/FAS	VISIT 11	08FEB2021	120/66	68.0	182.0	79.0
01/0149	ND plus	ES/SAF/FAS	VISIT 1	01DEC2015	146/98	78.0	164.0	75.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	02DEC2015	144/93	66.0	164.0	75.0
	ND plus	ES/SAF/FAS	VISIT 3A	01MAR2016	138/95	54.0	164.0	75.0
	ND plus	ES/SAF/FAS	VISIT 4	13APR2016	155/102	64.0	164.0	75.0
	ND plus	ES/SAF/FAS	VISIT 5	01JUN2016	154/100	59.0	164.0	80.0
	ND plus	ES/SAF/FAS	VISIT 6	14SEP2016	126/94	69.0	164.0	75.0
	ND plus	ES/SAF/FAS	VISIT 7	15MAR2017	145/95	68.0	164.0	75.0
	ND plus	ES/SAF/FAS	VISIT 8	14MAR2018	149/93	81.0	164.0	84.0
	ND plus	ES/SAF/FAS	VISIT 11	24FEB2021	138/95	86.0	164.0	75.0
01/0150		ES	VISIT 1	02FEB2016	130/85	95.0	168.0	56.0
		ES	BASELINE (VISIT 2A)	02FEB2016	130/85	95.0	168.0	56.0
01/0151	ND basic	ES/SAF/FAS	VISIT 1	01MAR2016	157/98	75.0	190.0	105.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
01/0151	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	01MAR2016	157/98	75.0	190.0	105.0
	ND basic	ES/SAF/FAS	VISIT 3A	07JUN2016	150/93	68.0	190.0	100.0
	ND basic	ES/SAF/FAS	VISIT 4	13JUL2016	140/88	72.0	190.0	100.0
	ND basic	ES/SAF/FAS	VISIT 5	07SEP2016	135/85	79.0	190.0	100.0
	ND basic	ES/SAF/FAS	VISIT 6	30NOV2016	138/88	89.0	190.0	100.0
	ND basic	ES/SAF/FAS	VISIT 7	31MAY2017	142/78	73.0	190.0	103.0
	ND basic	ES/SAF/FAS	VISIT 8	02MAY2018	134/86	88.0	190.0	105.0
	ND basic	ES/SAF/FAS	VISIT 11	12MAY2021	140/90	64.0	190.0	100.0
01/0152	SC	ES/SAF/FAS	VISIT 1	02MAR2016	140/98	102.0	160.0	49.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	02MAR2016	140/98	102.0	160.0	49.0
	SC	ES/SAF/FAS	VISIT 4	21APR2016	134/89	90.0	160.0	48.0
	SC	ES/SAF/FAS	VISIT 5	25MAY2016	135/82	89.0	160.0	49.0
	SC	ES/SAF/FAS	VISIT 6	24AUG2016	122/86	73.0	160.0	50.0
	SC	ES/SAF/FAS	VISIT 7	22FEB2017	129/83	81.0	160.0	50.0
	SC	ES/SAF/FAS	VISIT 8	07MAR2018	149/86	80.0	160.0	48.0
	SC	ES/SAF/FAS	VISIT 11	10MAR2021	134/85	72.0	160.0	49.0
01/0153	ND basic	ES/SAF/FAS	VISIT 1	18MAR2016	139/90	73.0	169.0	72.0
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	20MAR2016	134/92	96.0	169.0	72.0
	ND basic	ES/SAF/FAS	VISIT 3A	07JUN2016	139/98	78.0	169.0	70.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	22JUN2016	-/-	-	169.0	70.0
	ND basic	ES/SAF/FAS	VISIT 4	20JUL2016	132/94	86.0	169.0	70.0
	ND basic	ES/SAF/FAS	VISIT 5	07SEP2016	136/100	85.0	169.0	70.0
	ND basic	ES/SAF/FAS	VISIT 6	30NOV2016	130/93	78.0	169.0	75.0
	ND basic	ES/SAF/FAS	VISIT 7	31MAY2017	146/100	84.0	169.0	82.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	26JUL2017	130/89	87.0	169.0	82.0
	ND basic	ES/SAF/FAS	VISIT 8	02MAY2018	126/87	88.0	168.0	75.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	19NOV2018	121/83	80.0	169.0	64.0
	ND basic	ES/SAF/FAS	VISIT 11	14JUN2021	-/-	-	169.0	85.0
02/0201	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	13FEB2013	140/80	70.0	176.0	76.0
	ND plus	ES/SAF/FAS	VISIT 3A	07MAY2013	150/80	-	176.0	76.0
	ND plus	ES/SAF/FAS	VISIT 4	20JUN2013	130/80	76.0	176.0	76.0
	ND plus	ES/SAF/FAS	VISIT 5	31JUL2013	130/70	80.0	176.0	76.0
	ND plus	ES/SAF/FAS	VISIT 6	29OCT2013	140/70	80.0	176.0	76.0
	ND plus	ES/SAF/FAS	VISIT 7	06MAY2014	130/70	76.0	176.0	76.0
	ND plus	ES/SAF/FAS	VISIT 8	02JUN2015	140/80	88.0	176.0	76.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	28DEC2015	-/-	-	176.0	80.0
	ND plus	ES/SAF/FAS	VISIT 11	29MAY2018	130/80	88.0	176.0	85.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
02/0202	ND basic	ES/SAF	BASELINE (VISIT 2A)	19MAR2013	140/80	76.0	175.0	78.0
02/0203	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	28MAR2013	130/80	78.0	188.0	91.0
	ND basic	ES/SAF/FAS	VISIT 3A	25JUN2013	140/80	80.0	188.0	91.0
	ND basic	ES/SAF/FAS	VISIT 4	13AUG2013	120/80	80.0	188.0	90.0
	ND basic	ES/SAF/FAS	VISIT 5	24SEP2013	120/80	86.0	188.0	90.0
	ND basic	ES/SAF/FAS	VISIT 6	10DEC2013	145/80	80.0	188.0	91.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	26FEB2014	140/80	76.0	188.0	91.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	05MAR2014	120/70	88.0	188.0	91.0
	ND basic	ES/SAF/FAS	VISIT 7	26JUN2014	120/70	78.0	188.0	90.0
	ND basic	ES/SAF/FAS	VISIT 8	24JUN2015	130/80	80.0	186.0	90.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	20JUL2016	120/80	82.0	188.0	92.0
	ND basic	ES/SAF/FAS	VISIT 11	26JUN2018	120/80	76.0	188.0	91.0
02/0204	ND basic	ES/SAF	BASELINE (VISIT 2A)	17APR2013	110/60	78.0	185.0	75.0
02/0205	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	17APR2013	140/80	80.0	180.0	90.0
	ND basic	ES/SAF/FAS	VISIT 3A	30JUL2013	130/90	-	180.0	95.0
	ND basic	ES/SAF/FAS	VISIT 4	17SEP2013	160/80	-	180.0	95.0
	ND basic	ES/SAF/FAS	VISIT 5	28OCT2013	130/70	70.0	180.0	90.0
	ND basic	ES/SAF/FAS	VISIT 6	23JAN2014	140/80	80.0	180.0	95.0
	ND basic	ES/SAF/FAS	VISIT 7	12AUG2014	140/80	88.0	180.0	90.0
	ND basic	ES/SAF/FAS	VISIT 8	21AUG2015	130/80	80.0	180.0	95.0
	ND basic	ES/SAF/FAS	VISIT 11	28AUG2018	140/70	100.0	180.0	93.0
02/0206	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	27JUN2013	160/90	76.0	183.0	80.0
	ND plus	ES/SAF/FAS	VISIT 3A	07OCT2013	140/90	80.0	180.0	80.0
	ND plus	ES/SAF/FAS	VISIT 4	20NOV2013	140/80	80.0	180.0	83.0
	ND plus	ES/SAF/FAS	VISIT 5	03JAN2014	140/70	88.0	180.0	83.0
	ND plus	ES/SAF/FAS	VISIT 6	07MAR2014	140/80	64.0	180.0	80.0
	ND plus	ES/SAF/FAS	VISIT 7	11JUL2014	130/80	80.0	180.0	80.0
	ND plus	ES/SAF/FAS	VISIT 11	30AUG2018	130/70	68.0	180.0	73.5
02/0207		ES	BASELINE (VISIT 2A)	23JUL2013	155/90	-	183.0	94.0
02/0208	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	11SEP2013	100/65	64.0	186.0	62.0
	ND plus	ES/SAF/FAS	VISIT 3A	09DEC2013	125/70	82.0	186.0	66.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	16DEC2013	120/80	88.0	186.0	66.0
	ND plus	ES/SAF/FAS	VISIT 4	22JAN2014	120/70	76.0	186.0	65.0
	ND plus	ES/SAF/FAS	VISIT 5	25MAR2014	130/70	70.0	186.0	65.0

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set
Clinipace: 14DEC21 / 7:42 / l_vs.lst / l_vs.sas

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
02/0208	ND plus	ES/SAF/FAS	UNSCHEDULED	01APR2014	120/70	-	186.0	64.0
	ND plus	ES/SAF/FAS	VISIT 6	28MAY2014	140/70	76.0	186.0	64.0
	ND plus	ES/SAF/FAS	VISIT 7	30DEC2014	120/70	100.0	186.0	66.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	01SEP2015	110/70	80.0	186.0	65.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	21SEP2015	120/80	-	186.0	65.0
	ND plus	ES/SAF/FAS	VISIT 8	17DEC2015	115/60	76.0	186.0	68.0
	ND plus	ES/SAF/FAS	VISIT 11	27DEC2018	110/70	80.0	186.0	69.0
02/0209	ND plus	ES/SAF/FAS	VISIT 1	22OCT2014	140/80	80.0	178.0	82.0
	ND plus	ES/SAF/FAS	VISIT 3A	29JAN2015	120/80	78.0	176.0	80.0
	ND plus	ES/SAF/FAS	VISIT 4	24MAR2015	110/60	78.0	178.0	77.0
	ND plus	ES/SAF/FAS	VISIT 5	29APR2015	120/70	88.0	178.0	77.0
	ND plus	ES/SAF/FAS	VISIT 6	16JUL2015	120/70	88.0	175.0	76.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	05NOV2015	-/-	-	176.0	77.0
	ND plus	ES/SAF/FAS	VISIT 7	23FEB2016	130/70	80.0	176.0	80.0
	ND plus	ES/SAF/FAS	VISIT 8	19JAN2017	120/80	88.0	176.0	82.0
	ND plus	ES/SAF/FAS	VISIT 11	30DEC2019	115/70	88.0	178.0	83.0
02/0210		ES	VISIT 1	12NOV2014	150/80	80.0	170.0	103.0
		ES	BASELINE (VISIT 2A)	12NOV2014	150/80	80.0	170.0	103.0
02/0211	ND basic	ES/SAF	VISIT 1	10DEC2014	140/80	68.0	193.0	71.0
	ND basic	ES/SAF	BASELINE (VISIT 2A)	10DEC2014	140/80	68.0	193.0	71.0
	ND basic	ES/SAF	VISIT 3A	04MAR2015	130/80	80.0	193.0	73.0
02/0212	SC	ES/SAF/FAS	VISIT 1	15DEC2014	130/70	100.0	185.0	100.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	15DEC2014	130/70	100.0	185.0	100.0
	SC	ES/SAF/FAS	VISIT 4	30JAN2015	120/80	68.0	185.0	107.0
	SC	ES/SAF/FAS	VISIT 5	10APR2015	-/-	-	185.0	107.0
	SC	ES/SAF/FAS	VISIT 6	25JUN2015	120/80	66.0	185.0	108.0
	SC	ES/SAF/FAS	VISIT 7	28JAN2016	130/90	92.0	185.0	109.0
	SC	ES/SAF/FAS	VISIT 8	28DEC2016	140/80	80.0	185.0	108.0
	SC	ES/SAF/FAS	VISIT 11	27DEC2019	140/80	100.0	185.0	105.0
02/0213	ND plus	ES/SAF	BASELINE (VISIT 2A)	17DEC2014	120/60	78.0	167.0	64.0
02/0214	ND plus	ES/SAF/FAS	VISIT 1	24FEB2015	120/80	80.0	160.0	66.0
	ND plus	ES/SAF/FAS	VISIT 3A	27MAY2015	110/70	80.0	160.0	65.0
	ND plus	ES/SAF/FAS	VISIT 4	23JUL2015	110/60	100.0	160.0	66.0
	ND plus	ES/SAF/FAS	VISIT 6	03DEC2015	110/70	80.0	160.0	68.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
02/0214	ND plus	ES/SAF/FAS	VISIT 7	26MAY2016	110/60	100.0	160.0	66.0
	ND plus	ES/SAF/FAS	VISIT 11	15OCT2020	110/70	88.0	160.0	66.0
02/0215		ES	VISIT 1	04MAR2015	130/80	100.0	186.0	96.0
		ES	BASELINE (VISIT 2A)	04MAR2015	130/80	100.0	186.0	96.0
02/0216	ND plus	ES/SAF/FAS	VISIT 1	27APR2015	120/80	80.0	172.0	85.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	27APR2015	120/80	80.0	172.0	85.0
	ND plus	ES/SAF/FAS	VISIT 3A	22JUL2015	130/90	100.0	173.0	85.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	29JUL2015	-/-	-	173.0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	07AUG2015	-/-	-	173.0	-
	ND plus	ES/SAF/FAS	VISIT 5	21OCT2015	120/70	80.0	172.0	80.0
02/0217	SC	ES/SAF/FAS	VISIT 1	27MAY2015	130/80	80.0	185.0	93.5
	SC	ES/SAF/FAS	VISIT 4	14JUL2015	120/80	80.0	185.0	91.0
	SC	ES/SAF/FAS	VISIT 5	30AUG2015	120/80	88.0	185.0	95.0
	SC	ES/SAF/FAS	VISIT 6	08DEC2015	130/80	76.0	185.0	89.0
	SC	ES/SAF/FAS	VISIT 7	11MAY2016	120/70	100.0	183.0	85.0
	SC	ES/SAF/FAS	VISIT 8	27APR2017	130/80	86.0	182.0	90.0
	SC	ES/SAF/FAS	VISIT 11	01JUL2020	130/70	88.0	185.0	100.0
02/0218	ND basic	ES/SAF	VISIT 1	16JUN2015	-/-	-	164.0	63.0
	ND basic	ES/SAF	BASELINE (VISIT 2A)	29JUN2015	129/78	68.0	163.0	63.0
02/0219	ND basic	ES/SAF/FAS	VISIT 1	10JUN2015	120/80	80.0	167.0	72.0
	ND basic	ES/SAF/FAS	VISIT 3A	24SEP2015	130/70	80.0	167.0	72.0
	ND basic	ES/SAF/FAS	VISIT 4	04NOV2015	120/80	76.0	167.0	72.0
	ND basic	ES/SAF/FAS	VISIT 5	17DEC2015	130/70	80.0	167.0	72.0
	ND basic	ES/SAF/FAS	VISIT 6	04APR2016	120/80	76.0	167.0	72.0
	ND basic	ES/SAF/FAS	VISIT 7	22AUG2016	120/70	100.0	167.0	72.0
	ND basic	ES/SAF/FAS	VISIT 8	20SEP2017	120/70	100.0	167.0	72.0
	ND basic	ES/SAF/FAS	VISIT 11	26AUG2020	125/80	88.0	165.0	84.0
02/0220	SC	ES/SAF/FAS	VISIT 1	12AUG2015	100/60	80.0	158.0	88.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	12AUG2015	100/60	80.0	158.0	88.0
	SC	ES/SAF/FAS	VISIT 4	29SEP2015	110/70	88.0	158.0	90.0
	SC	ES/SAF/FAS	VISIT 5	17NOV2015	120/70	80.0	158.0	90.0
	SC	ES/SAF/FAS	VISIT 6	26JAN2016	130/80	88.0	158.0	92.0
	SC	ES/SAF/FAS	VISIT 7	04AUG2016	130/70	100.0	158.0	90.0
	SC	ES/SAF/FAS	VISIT 8	19JUL2017	130/70	88.0	158.0	90.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
02/0220	SC	ES/SAF/FAS	VISIT 11	02SEP2020	140/70	80.0	158.0	84.0
02/0221	ND plus	ES/SAF	VISIT 1	31AUG2015	120/90	80.0	164.0	61.0
	ND plus	ES/SAF	VISIT 3A	10DEC2015	130/80	88.0	164.0	62.0
02/0222	ND plus	ES/SAF	VISIT 1	09SEP2015	167/100	73.0	180.0	103.0
02/0223	ND basic	ES/SAF/FAS	VISIT 1	28DEC2015	110/60	80.0	158.0	58.0
	ND basic	ES/SAF/FAS	VISIT 3A	21MAR2016	110/70	-	158.0	57.0
	ND basic	ES/SAF/FAS	VISIT 4	27APR2016	110/80	76.0	158.0	57.0
	ND basic	ES/SAF/FAS	VISIT 5	05JUL2016	115/70	76.0	158.0	57.0
	ND basic	ES/SAF/FAS	VISIT 6	24AUG2016	110/70	80.0	158.0	57.0
	ND basic	ES/SAF/FAS	VISIT 7	15MAR2017	120/70	60.0	158.0	58.0
	ND basic	ES/SAF/FAS	VISIT 8	07MAR2018	130/80	88.0	158.0	57.0
	ND basic	ES/SAF/FAS	VISIT 11	03MAR2021	125/70	80.0	158.0	60.0
02/0224	ND plus	ES/SAF	VISIT 1	28DEC2015	120/80	72.0	169.0	55.0
04/0401	SC	ES/SAF/FAS	VISIT 1	24JUN2015	130/70	88.0	172.0	72.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	24JUN2015	128/70	82.0	172.0	72.0
	SC	ES/SAF/FAS	VISIT 4	11AUG2015	125/80	84.0	172.0	76.0
	SC	ES/SAF/FAS	VISIT 5	08OCT2015	130/80	80.0	172.0	76.0
	SC	ES/SAF/FAS	VISIT 6	16DEC2015	109/58	78.0	172.0	76.0
	SC	ES/SAF/FAS	VISIT 7	21JUN2016	130/85	68.0	172.0	75.0
	SC	ES/SAF/FAS	VISIT 8	05JUL2017	126/64	68.0	172.0	77.0
	SC	ES/SAF/FAS	VISIT 11	27JUL2020	120/85	80.0	172.0	88.0
06/0602	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	22JUL2013	140/80	85.0	164.0	67.0
	ND plus	ES/SAF/FAS	VISIT 3A	04NOV2013	140/70	64.0	164.0	67.0
	ND plus	ES/SAF/FAS	VISIT 4	18DEC2013	120/80	66.0	165.0	75.0
	ND plus	ES/SAF/FAS	VISIT 5	12FEB2014	120/80	79.0	164.0	67.0
	ND plus	ES/SAF/FAS	VISIT 6	22APR2014	110/75	66.0	163.0	63.0
	ND plus	ES/SAF/FAS	VISIT 7	23OCT2014	125/65	68.0	163.0	67.0
	ND plus	ES/SAF/FAS	VISIT 8	18NOV2015	110/70	60.0	164.0	61.0
06/0604	ND basic	ES/SAF	VISIT 1	27OCT2014	130/80	90.0	190.0	90.0
	ND basic	ES/SAF	BASELINE (VISIT 2A)	27OCT2014	130/80	90.0	190.0	90.0
06/0605	ND plus	ES/SAF	VISIT 1	10DEC2014	120/70	72.0	187.0	99.0
	ND plus	ES/SAF	BASELINE (VISIT 2A)	11DEC2014	120/70	72.0	187.0	99.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
06/0606	SC	ES/SAF/FAS	VISIT 1	15DEC2014	150/100	80.0	160.0	85.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	15DEC2014	150/100	80.0	160.0	85.0
	SC	ES/SAF/FAS	VISIT 4	10FEB2015	120/75	92.0	160.0	87.0
	SC	ES/SAF/FAS	VISIT 5	12MAR2015	130/90	74.0	160.0	89.0
	SC	ES/SAF/FAS	VISIT 6	03JUN2015	135/75	72.0	160.0	89.0
	SC	ES/SAF/FAS	VISIT 7	03DEC2015	130/90	85.0	160.0	89.0
	SC	ES/SAF/FAS	VISIT 8	24NOV2016	130/85	70.0	160.0	95.0
	SC	ES/SAF/FAS	VISIT 11	03DEC2019	170/100	80.0	160.0	98.0
06/0607	ND plus	ES/SAF/FAS	VISIT 1	19JAN2015	120/70	66.0	160.0	75.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	19JAN2015	120/70	66.0	160.0	75.0
	ND plus	ES/SAF/FAS	VISIT 3A	14APR2015	120/70	76.0	160.0	75.0
	ND plus	ES/SAF/FAS	VISIT 4	01JUN2015	130/85	85.0	160.0	75.0
	ND plus	ES/SAF/FAS	VISIT 5	21JUL2015	120/95	88.0	160.0	76.0
	ND plus	ES/SAF/FAS	VISIT 6	06OCT2015	120/85	90.0	160.0	76.0
	ND plus	ES/SAF/FAS	VISIT 7	05APR2016	135/95	88.0	160.0	78.0
	ND plus	ES/SAF/FAS	VISIT 8	05APR2017	120/80	88.0	160.0	80.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	28MAR2018	-/-	-	160.0	80.0
06/0608	SC	ES/SAF	VISIT 1	27JAN2015	110/70	75.0	175.0	82.0
	SC	ES/SAF	BASELINE (VISIT 2A)	27JAN2015	110/70	75.0	175.0	82.0
06/0609	ND basic	ES/SAF	VISIT 1	15APR2015	115/80	75.0	165.0	70.0
	ND basic	ES/SAF	BASELINE (VISIT 2A)	15APR2015	115/80	75.0	165.0	70.0
06/0610	ND plus	ES/SAF/FAS	VISIT 1	24JUN2015	90/60	68.0	164.0	69.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	24JUN2015	90/60	68.0	164.0	69.0
	ND plus	ES/SAF/FAS	VISIT 3A	07SEP2015	130/80	76.0	163.0	71.0
	ND plus	ES/SAF/FAS	VISIT 4	26OCT2015	105/70	60.0	163.0	74.0
	ND plus	ES/SAF/FAS	VISIT 5	14DEC2015	115/80	68.0	163.0	69.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	19JAN2016	110/80	76.0	163.0	67.0
	ND plus	ES/SAF/FAS	VISIT 6	16MAR2016	110/70	68.0	163.0	65.0
	ND plus	ES/SAF/FAS	VISIT 7	30AUG2016	115/85	76.0	163.0	63.0
	ND plus	ES/SAF/FAS	VISIT 8	10OCT2017	-/-	-	163.0	62.0
	ND plus	ES/SAF/FAS	VISIT 11	07SEP2020	-/-	-	163.0	57.0
06/0611		ES	VISIT 1	14JUL2015	140/80	72.0	180.0	85.0
		ES	BASELINE (VISIT 2A)	14JUL2015	140/80	72.0	180.0	85.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
06/0612	ND plus	ES/SAF/FAS	VISIT 1	14JUL2015	130/90	88.0	185.0	85.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	14JUL2015	130/90	88.0	185.0	85.0
	ND plus	ES/SAF/FAS	VISIT 3A	19OCT2015	110/60	72.0	185.0	87.0
	ND plus	ES/SAF/FAS	VISIT 4	25NOV2015	130/80	76.0	185.0	89.0
	ND plus	ES/SAF/FAS	VISIT 5	11JAN2016	145/80	76.0	185.0	90.0
	ND plus	ES/SAF/FAS	VISIT 6	11APR2016	130/75	76.0	185.0	91.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	19MAY2016	-/-	-	185.0	91.0
	ND plus	ES/SAF/FAS	VISIT 7	26OCT2016	115/70	72.0	185.0	92.0
	ND plus	ES/SAF/FAS	VISIT 8	19OCT2017	140/90	80.0	185.0	95.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	28NOV2019	130/90	84.0	185.0	95.0
	ND plus	ES/SAF/FAS	VISIT 11	14OCT2020	120/80	68.0	185.0	89.0
06/0613	SC	ES/SAF/FAS	VISIT 1	17JUL2015	120/80	68.0	178.0	81.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	17JUL2015	120/80	68.0	178.0	81.0
	SC	ES/SAF/FAS	VISIT 4	04SEP2015	125/70	56.0	178.0	81.0
	SC	ES/SAF/FAS	VISIT 5	16OCT2015	120/70	72.0	178.0	81.0
	SC	ES/SAF/FAS	VISIT 6	15JAN2016	110/70	66.0	178.0	81.0
	SC	ES/SAF/FAS	VISIT 7	15JUL2016	125/80	58.0	178.0	81.0
	SC	ES/SAF/FAS	VISIT 8	09AUG2017	115/70	60.0	178.0	81.0
	SC	ES/SAF/FAS	VISIT 11	11AUG2020	-/-	-	178.0	80.0
06/0614	ND plus	ES/SAF/FAS	VISIT 1	14AUG2015	130/70	80.0	187.0	75.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	14AUG2015	130/70	80.0	187.0	75.0
	ND plus	ES/SAF/FAS	VISIT 3A	16NOV2015	120/80	72.0	188.0	75.0
	ND plus	ES/SAF/FAS	VISIT 4	04JAN2016	115/70	64.0	187.0	75.0
	ND plus	ES/SAF/FAS	VISIT 5	09FEB2016	120/90	84.0	187.0	74.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	22FEB2016	-/-	-	187.0	74.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	10MAR2016	110/80	60.0	187.0	75.0
	ND plus	ES/SAF/FAS	VISIT 6	02MAY2016	105/75	68.0	187.0	75.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	03AUG2016	110/85	74.0	187.0	77.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	10AUG2016	120/80	72.0	187.0	77.0
	ND plus	ES/SAF/FAS	VISIT 7	17NOV2016	130/80	80.0	187.0	74.0
	ND plus	ES/SAF/FAS	VISIT 8	02NOV2017	130/80	108.0	187.0	75.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	15NOV2017	-/-	-	187.0	-
	ND plus	ES/SAF/FAS	VISIT 11	10DEC2020	110/80	64.0	187.0	82.0
06/0615	ND basic	ES/SAF	VISIT 1	21AUG2015	115/80	60.0	175.0	70.0
	ND basic	ES/SAF	BASELINE (VISIT 2A)	21AUG2015	115/80	60.0	175.0	70.0
06/0616		ES	VISIT 1	05NOV2015	130/80	76.0	171.0	90.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
06/0616		ES	BASELINE (VISIT 2A)	05NOV2015	130/80	76.0	171.0	90.0
06/0617	ND plus	ES/SAF	VISIT 1	21DEC2015	140/90	80.0	180.0	87.0
	ND plus	ES/SAF	BASELINE (VISIT 2A)	21DEC2015	140/90	80.0	180.0	87.0
	ND plus	ES/SAF	VISIT 3A	08MAR2016	130/95	72.0	180.0	90.0
06/0618		ES	VISIT 1	14JAN2016	120/80	72.0	178.0	86.0
		ES	BASELINE (VISIT 2A)	14JAN2016	120/80	72.0	178.0	86.0
06/0619	ND basic	ES/SAF/FAS	VISIT 1	22FEB2016	140/90	62.0	190.0	109.0
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	22FEB2016	140/90	62.0	190.0	109.0
	ND basic	ES/SAF/FAS	VISIT 3A	09MAY2016	160/90	84.0	190.0	110.0
	ND basic	ES/SAF/FAS	VISIT 4	20JUN2016	140/80	60.0	190.0	107.0
	ND basic	ES/SAF/FAS	VISIT 5	04AUG2016	-/-	-	190.0	109.0
	ND basic	ES/SAF/FAS	VISIT 6	03NOV2016	130/80	88.0	190.0	106.0
	ND basic	ES/SAF/FAS	VISIT 7	15MAY2017	170/95	80.0	190.0	109.0
	ND basic	ES/SAF/FAS	VISIT 8	02MAY2018	145/80	88.0	190.0	120.0
	ND basic	ES/SAF/FAS	VISIT 11	28MAY2021	130/80	80.0	190.0	120.0
06/0620	SC	ES/SAF/FAS	VISIT 1	23FEB2016	120/80	78.0	185.0	105.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	23FEB2016	120/80	78.0	185.0	105.0
	SC	ES/SAF/FAS	VISIT 4	12APR2016	115/80	64.0	185.0	98.0
	SC	ES/SAF/FAS	VISIT 5	23MAY2016	125/80	80.0	185.0	100.0
	SC	ES/SAF/FAS	VISIT 6	17AUG2016	130/85	72.0	185.0	100.0
	SC	ES/SAF/FAS	VISIT 7	20FEB2017	120/90	72.0	185.0	98.0
	SC	ES/SAF/FAS	VISIT 8	26MAR2018	115/80	68.0	185.0	100.0
	SC	ES/SAF/FAS	VISIT 11	02MAR2021	140/80	68.0	185.0	105.0
07/0701	ND plus	ES/SAF/FAS	VISIT 1	04NOV2014	115/75	64.0	164.0	50.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	05NOV2014	110/60	62.0	164.0	50.0
	ND plus	ES/SAF/FAS	VISIT 3A	19JAN2015	110/60	64.0	164.0	51.0
	ND plus	ES/SAF/FAS	VISIT 4	04MAR2015	110/60	68.0	165.0	50.0
	ND plus	ES/SAF/FAS	VISIT 5	27APR2015	110/65	84.0	164.0	51.0
	ND plus	ES/SAF/FAS	VISIT 6	20JUL2015	100/60	76.0	164.0	51.0
	ND plus	ES/SAF/FAS	VISIT 7	14JAN2016	110/70	76.0	165.0	51.0
	ND plus	ES/SAF/FAS	VISIT 8	30JAN2017	110/70	88.0	164.0	51.0
	ND plus	ES/SAF/FAS	VISIT 11	12FEB2020	110/65	74.0	164.0	53.0
07/0702	SC	ES/SAF/FAS	VISIT 1	19JAN2015	110/70	80.0	170.0	70.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	19JAN2015	110/70	80.0	170.0	70.0

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set
Clinipace: 14DEC21 / 7:42 / l_vs.lst / l_vs.sas

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
07/0702	SC	ES/SAF/FAS	VISIT 4	02MAR2015	120/70	60.0	170.0	70.0
	SC	ES/SAF/FAS	VISIT 5	20APR2015	110/70	72.0	170.0	70.0
	SC	ES/SAF/FAS	VISIT 6	21JUL2015	120/60	64.0	170.0	60.0
	SC	ES/SAF/FAS	VISIT 8	14FEB2018	120/70	74.0	170.0	70.0
07/0703	ND plus	ES/SAF/FAS	VISIT 1	27FEB2015	140/82	86.0	178.0	73.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	02MAR2015	140/82	80.0	178.0	73.0
	ND plus	ES/SAF/FAS	VISIT 3A	18MAY2015	130/80	76.0	178.0	74.0
	ND plus	ES/SAF/FAS	VISIT 4	29JUN2015	130/75	80.0	178.0	75.0
	ND plus	ES/SAF/FAS	VISIT 5	17AUG2015	130/70	76.0	178.0	76.0
	ND plus	ES/SAF/FAS	VISIT 6	09NOV2015	140/90	84.0	178.0	81.0
	ND plus	ES/SAF/FAS	VISIT 7	09MAY2016	130/80	80.0	178.0	74.0
	ND plus	ES/SAF/FAS	VISIT 8	24APR2017	120/80	76.0	178.0	67.0
	ND plus	ES/SAF/FAS	VISIT 11	20JUL2020	125/80	78.0	178.0	76.0
07/0704	ND basic	ES/SAF/FAS	VISIT 1	14JUL2015	130/90	84.0	170.0	73.0
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	15JUL2015	130/90	80.0	170.0	73.0
	ND basic	ES/SAF/FAS	VISIT 3A	06OCT2015	110/70	72.0	170.0	72.0
	ND basic	ES/SAF/FAS	VISIT 4	16NOV2015	110/70	68.0	170.0	72.0
	ND basic	ES/SAF/FAS	VISIT 5	11JAN2016	125/80	65.0	170.0	72.0
	ND basic	ES/SAF/FAS	VISIT 6	11APR2016	120/80	72.0	170.0	71.0
	ND basic	ES/SAF/FAS	VISIT 7	21NOV2016	130/80	80.0	170.0	71.0
	ND basic	ES/SAF/FAS	VISIT 8	02OCT2017	110/70	68.0	170.0	72.0
	ND basic	ES/SAF/FAS	VISIT 11	21SEP2020	120/80	70.0	170.0	74.0
07/0705		ES	VISIT 1	11AUG2015	110/60	72.0	179.0	74.0
		ES	BASELINE (VISIT 2A)	12AUG2015	110/60	76.0	179.0	74.0
07/0706	SC	ES/SAF/FAS	VISIT 1	30NOV2015	110/80	60.0	184.0	110.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	30NOV2015	110/80	60.0	184.0	110.0
	SC	ES/SAF/FAS	VISIT 4	12JAN2016	125/85	84.0	184.0	111.0
07/0707		ES	VISIT 1	18FEB2016	120/60	72.0	164.0	68.0
		ES	BASELINE (VISIT 2A)	20FEB2016	120/60	80.0	164.0	68.0
08/0801	SC	ES/SAF/FAS	VISIT 1	31OCT2014	140/80	72.0	175.0	62.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	02NOV2014	130/95	64.0	175.0	62.0
	SC	ES/SAF/FAS	VISIT 4	22DEC2014	140/100	92.0	175.0	66.0
	SC	ES/SAF/FAS	VISIT 5	12FEB2015	130/80	64.0	175.0	65.0
	SC	ES/SAF/FAS	VISIT 6	04MAY2015	130/85	64.0	175.0	65.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
08/0802	ND plus	ES/SAF/FAS	VISIT 1	26NOV2014	130/70	64.0	158.0	55.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	26NOV2014	130/70	64.0	158.0	55.0
	ND plus	ES/SAF/FAS	VISIT 3A	03MAR2015	110/70	72.0	158.0	55.0
	ND plus	ES/SAF/FAS	VISIT 4	08APR2015	120/70	60.0	158.0	55.0
	ND plus	ES/SAF/FAS	VISIT 5	01JUN2015	110/70	72.0	158.0	55.0
	ND plus	ES/SAF/FAS	VISIT 6	17AUG2015	120/75	64.0	158.0	55.0
	ND plus	ES/SAF/FAS	VISIT 7	22FEB2016	130/70	56.0	158.0	55.0
	ND plus	ES/SAF/FAS	VISIT 8	02FEB2017	117/78	66.0	158.0	55.0
	ND plus	ES/SAF/FAS	VISIT 11	19MAR2020	130/85	60.0	158.0	58.0
08/0803	ND basic	ES/SAF/FAS	VISIT 1	24FEB2015	140/90	65.0	193.0	91.0
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	24FEB2015	140/90	65.0	193.0	91.0
	ND basic	ES/SAF/FAS	VISIT 3A	15JUN2015	140/90	65.0	192.0	95.0
	ND basic	ES/SAF/FAS	VISIT 4	24JUL2015	136/92	66.0	192.0	95.0
	ND basic	ES/SAF/FAS	VISIT 5	07SEP2015	140/85	64.0	192.0	96.0
08/0804	ND plus	ES/SAF/FAS	VISIT 1	02JUN2015	125/85	80.0	198.0	115.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	02JUN2015	125/85	80.0	198.0	115.0
	ND plus	ES/SAF/FAS	VISIT 3A	20AUG2015	105/85	72.0	198.0	115.0
	ND plus	ES/SAF/FAS	VISIT 4	28SEP2015	125/85	52.0	198.0	111.0
	ND plus	ES/SAF/FAS	VISIT 5	13NOV2015	130/75	66.0	198.0	112.0
	ND plus	ES/SAF/FAS	VISIT 6	05FEB2016	120/75	48.0	198.0	112.0
	ND plus	ES/SAF/FAS	VISIT 7	22AUG2016	140/90	56.0	198.0	113.0
	ND plus	ES/SAF/FAS	VISIT 8	04AUG2017	125/90	60.0	198.0	115.0
	ND plus	ES/SAF/FAS	VISIT 11	04AUG2020	120/90	56.0	198.0	115.0
08/0805	ND basic	ES/SAF/FAS	VISIT 1	19JUN2015	140/85	72.0	166.0	90.0
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	24JUN2015	-/-	-	166.0	-
	ND basic	ES/SAF/FAS	VISIT 3A	21SEP2015	135/90	66.0	166.0	90.0
	ND basic	ES/SAF/FAS	VISIT 4	02NOV2015	140/80	68.0	166.0	91.0
	ND basic	ES/SAF/FAS	VISIT 5	21DEC2015	130/90	78.0	166.0	92.0
	ND basic	ES/SAF/FAS	VISIT 6	07MAR2016	145/95	80.0	166.0	90.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	24JUN2016	130/75	82.0	166.0	90.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	28JUL2016	140/84	68.0	166.0	90.0
	ND basic	ES/SAF/FAS	VISIT 7	14FEB2017	125/85	64.0	166.0	90.0
	ND basic	ES/SAF/FAS	VISIT 8	28AUG2017	130/80	72.0	166.0	94.0
	ND basic	ES/SAF/FAS	VISIT 11	03SEP2020	145/90	80.0	166.0	95.0
08/0806	ND plus	ES/SAF/FAS	VISIT 1	07JUL2015	120/80	72.0	180.0	77.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	07JUL2015	120/80	72.0	180.0	77.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
08/0806	ND plus	ES/SAF/FAS	VISIT 3A	28SEP2015	120/70	68.0	180.0	78.0
	ND plus	ES/SAF/FAS	VISIT 4	06NOV2015	145/85	84.0	180.0	78.0
	ND plus	ES/SAF/FAS	VISIT 5	23DEC2015	135/85	78.0	180.0	78.0
	ND plus	ES/SAF/FAS	VISIT 6	14MAR2016	135/85	84.0	180.0	80.0
	ND plus	ES/SAF/FAS	VISIT 7	27SEP2016	130/90	68.0	180.0	78.0
	ND plus	ES/SAF/FAS	VISIT 8	12OCT2017	110/70	72.0	180.0	67.0
	ND plus	ES/SAF/FAS	VISIT 11	24SEP2020	135/80	68.0	180.0	75.0
08/0807	ND plus	ES/SAF/FAS	VISIT 1	18NOV2015	130/90	76.0	172.0	56.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	18NOV2015	130/90	76.0	172.0	56.0
	ND plus	ES/SAF/FAS	VISIT 3A	01FEB2016	140/80	72.0	172.0	59.0
	ND plus	ES/SAF/FAS	VISIT 4	08MAR2016	160/100	92.0	172.0	59.0
	ND plus	ES/SAF/FAS	VISIT 5	03MAY2016	165/90	80.0	172.0	59.0
	ND plus	ES/SAF/FAS	VISIT 6	28JUL2016	150/95	78.0	172.0	63.0
	ND plus	ES/SAF/FAS	VISIT 7	06FEB2017	160/95	64.0	172.0	65.0
	ND plus	ES/SAF/FAS	VISIT 8	19FEB2018	145/100	76.0	172.0	61.0
08/0808	SC	ES/SAF/FAS	VISIT 1	02DEC2015	130/80	82.0	180.0	80.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	02DEC2015	135/90	76.0	180.0	80.0
	SC	ES/SAF/FAS	VISIT 4	07JAN2016	170/97	70.0	180.0	80.0
	SC	ES/SAF/FAS	VISIT 5	26FEB2016	135/90	64.0	180.0	79.0
	SC	ES/SAF/FAS	VISIT 6	03JUN2016	120/80	72.0	180.0	78.0
	SC	ES/SAF/FAS	VISIT 7	28NOV2016	140/80	64.0	180.0	79.0
	SC	ES/SAF/FAS	VISIT 8	13NOV2017	110/75	60.0	180.0	80.0
09/0901	SC	ES/SAF/FAS	VISIT 1	27OCT2014	130/80	84.0	185.0	83.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	29OCT2014	130/80	84.0	185.0	83.0
	SC	ES/SAF/FAS	VISIT 4	08DEC2014	130/85	76.0	184.0	85.0
	SC	ES/SAF/FAS	VISIT 5	27JAN2015	125/80	64.0	184.0	86.0
	SC	ES/SAF/FAS	VISIT 6	05MAY2015	120/75	80.0	185.0	86.0
	SC	ES/SAF/FAS	VISIT 7	03NOV2015	120/80	72.0	185.0	86.0
	SC	ES/SAF/FAS	VISIT 8	22NOV2016	110/70	72.0	185.0	86.0
	SC	ES/SAF/FAS	VISIT 11	28OCT2019	128/85	72.0	185.0	82.0
09/0902		ES	VISIT 1	12NOV2014	135/75	86.0	165.0	66.0
09/0903	ND plus	ES/SAF	VISIT 1	19NOV2014	140/85	72.0	179.0	81.0
	ND plus	ES/SAF	BASELINE (VISIT 2A)	19NOV2014	140/85	72.0	179.0	81.0
	ND plus	ES/SAF	VISIT 3A	11FEB2015	120/80	68.0	179.0	82.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
09/0904	ND basic	ES/SAF/FAS	VISIT 1	05FEB2015	125/70	80.0	175.0	89.5
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	05FEB2015	125/70	80.0	175.0	90.0
	ND basic	ES/SAF/FAS	VISIT 3A	20MAY2015	130/85	76.0	175.0	90.0
	ND basic	ES/SAF/FAS	VISIT 4	08JUL2015	120/85	72.0	175.0	90.0
	ND basic	ES/SAF/FAS	VISIT 5	26AUG2015	110/80	68.0	175.0	89.0
	ND basic	ES/SAF/FAS	VISIT 6	17NOV2015	125/85	80.0	175.0	89.0
	ND basic	ES/SAF/FAS	VISIT 7	23MAY2016	120/80	72.0	175.0	90.0
	ND basic	ES/SAF/FAS	VISIT 8	24APR2017	130/80	80.0	175.0	91.0
	ND basic	ES/SAF/FAS	VISIT 11	11MAY2020	120/80	76.0	175.0	92.0
09/0905	ND plus	ES/SAF/FAS	VISIT 1	18MAR2015	130/70	76.0	171.0	67.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	18MAR2015	130/70	76.0	171.0	67.0
	ND plus	ES/SAF/FAS	VISIT 3A	24JUN2015	120/85	72.0	171.0	70.0
	ND plus	ES/SAF/FAS	VISIT 4	10AUG2015	130/70	72.0	171.0	70.0
	ND plus	ES/SAF/FAS	VISIT 5	28SEP2015	120/80	76.0	171.0	70.0
	ND plus	ES/SAF/FAS	VISIT 6	21DEC2015	120/80	80.0	171.0	74.0
	ND plus	ES/SAF/FAS	VISIT 7	20JUN2016	125/80	72.0	171.0	74.0
	ND plus	ES/SAF/FAS	VISIT 8	19JUN2017	120/80	72.0	171.0	74.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	26SEP2018	140/80	72.0	171.0	73.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	20FEB2019	140/80	60.0	171.0	76.0
	ND plus	ES/SAF/FAS	VISIT 11	25MAY2020	115/80	72.0	171.0	74.0
09/0906		ES	VISIT 1	26MAR2015	130/90	72.0	168.0	56.0
09/0907	SC	ES/SAF/FAS	VISIT 1	13APR2015	140/80	64.0	189.0	82.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	13APR2015	140/80	64.0	189.0	82.0
	SC	ES/SAF/FAS	VISIT 4	26MAY2015	130/80	76.0	189.0	80.0
	SC	ES/SAF/FAS	VISIT 5	14JUL2015	120/70	76.0	189.0	78.0
	SC	ES/SAF/FAS	VISIT 6	09NOV2015	120/70	72.0	189.0	81.0
	SC	ES/SAF/FAS	VISIT 7	04APR2016	120/70	80.0	189.0	82.0
	SC	ES/SAF/FAS	VISIT 8	10APR2017	120/70	64.0	189.0	83.0
	SC	ES/SAF/FAS	VISIT 11	12MAY2020	125/80	72.0	189.0	84.0
09/0908	ND basic	ES/SAF/FAS	VISIT 1	05MAY2015	140/80	76.0	180.0	85.0
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	05MAY2015	140/80	76.0	180.0	85.0
	ND basic	ES/SAF/FAS	VISIT 3A	05AUG2015	120/70	76.0	180.0	80.0
	ND basic	ES/SAF/FAS	VISIT 4	21SEP2015	120/75	72.0	181.0	77.0
	ND basic	ES/SAF/FAS	VISIT 5	02NOV2015	115/70	80.0	181.0	76.0
	ND basic	ES/SAF/FAS	VISIT 6	25JAN2016	130/70	76.0	180.0	75.0
	ND basic	ES/SAF/FAS	VISIT 7	20JUL2016	125/75	76.0	180.0	73.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
09/0908	ND basic	ES/SAF/FAS	VISIT 8	17JUL2017	120/80	76.0	180.0	78.0
	ND basic	ES/SAF/FAS	VISIT 11	22JUN2020	125/80	76.0	180.0	84.0
09/0909	ND plus	ES/SAF/FAS	VISIT 1	11MAY2015	125/80	72.0	175.0	70.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	11MAY2015	125/80	72.0	175.0	70.0
	ND plus	ES/SAF/FAS	VISIT 3A	12AUG2015	110/70	60.0	175.0	70.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	20AUG2015	120/70	72.0	175.0	70.0
	ND plus	ES/SAF/FAS	VISIT 4	28SEP2015	130/80	64.0	175.0	71.0
	ND plus	ES/SAF/FAS	VISIT 5	09NOV2015	110/70	76.0	175.0	71.0
	ND plus	ES/SAF/FAS	VISIT 6	01FEB2016	120/75	80.0	175.0	71.0
	ND plus	ES/SAF/FAS	VISIT 7	18JUL2016	130/80	68.0	175.0	71.0
	ND plus	ES/SAF/FAS	VISIT 8	24JUL2017	120/70	68.0	175.0	71.0
	ND plus	ES/SAF/FAS	VISIT 11	27JUL2020	110/75	76.0	175.0	71.5
09/0910	ND plus	ES/SAF	VISIT 1	31AUG2015	150/80	72.0	183.0	112.0
	ND plus	ES/SAF	BASELINE (VISIT 2A)	31AUG2015	150/80	72.0	183.0	112.0
09/0911	ND plus	ES/SAF/FAS	VISIT 1	15OCT2015	130/85	80.0	170.0	88.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	15OCT2015	130/85	80.0	170.0	88.0
	ND plus	ES/SAF/FAS	VISIT 3A	13JAN2016	120/80	80.0	170.0	89.0
	ND plus	ES/SAF/FAS	VISIT 4	22FEB2016	115/60	72.0	170.0	87.0
	ND plus	ES/SAF/FAS	VISIT 5	11APR2016	120/85	72.0	170.0	87.0
	ND plus	ES/SAF/FAS	VISIT 6	04JUL2016	125/80	68.0	170.0	90.0
	ND plus	ES/SAF/FAS	VISIT 7	16JAN2017	120/80	76.0	170.0	87.0
	ND plus	ES/SAF/FAS	VISIT 8	29JAN2018	120/80	72.0	170.0	80.0
	ND plus	ES/SAF/FAS	VISIT 11	18JAN2021	120/80	68.0	170.0	94.6
09/0912	ND plus	ES/SAF/FAS	VISIT 1	19OCT2015	120/80	84.0	186.0	86.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	19OCT2015	120/80	84.0	186.0	86.0
	ND plus	ES/SAF/FAS	VISIT 3A	20JAN2016	120/70	60.0	186.0	85.0
	ND plus	ES/SAF/FAS	VISIT 4	29FEB2016	120/80	76.0	186.0	82.0
	ND plus	ES/SAF/FAS	VISIT 5	25APR2016	130/80	60.0	186.0	82.0
	ND plus	ES/SAF/FAS	VISIT 6	25JUL2016	115/80	76.0	186.0	84.0
	ND plus	ES/SAF/FAS	VISIT 7	23JAN2017	120/80	64.0	186.0	84.0
	ND plus	ES/SAF/FAS	VISIT 8	15JAN2018	120/80	64.0	186.0	85.0
	ND plus	ES/SAF/FAS	VISIT 11	25JAN2021	130/80	84.0	186.0	85.0
09/0913	ND basic	ES/SAF/FAS	VISIT 1	26NOV2015	115/70	68.0	178.0	73.0
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	26NOV2015	115/70	68.0	178.0	73.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	03DEC2015	120/60	64.0	178.0	73.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
09/0913	ND basic	ES/SAF/FAS	VISIT 3A	17FEB2016	100/70	72.0	178.0	72.0
	ND basic	ES/SAF/FAS	VISIT 4	04APR2016	115/70	76.0	178.0	73.0
	ND basic	ES/SAF/FAS	VISIT 5	23MAY2016	120/70	72.0	178.0	73.0
	ND basic	ES/SAF/FAS	VISIT 6	01AUG2016	120/75	72.0	178.0	73.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	25JAN2017	125/85	80.0	178.0	73.0
	ND basic	ES/SAF/FAS	VISIT 7	30JAN2017	130/70	80.0	178.0	73.0
	ND basic	ES/SAF/FAS	VISIT 8	05FEB2018	130/70	80.0	178.0	73.0
	ND basic	ES/SAF/FAS	VISIT 11	08MAR2021	130/70	64.0	178.0	67.0
09/0914	SC	ES/SAF/FAS	VISIT 1	04JAN2016	120/80	72.0	182.0	80.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	04JAN2016	120/80	72.0	182.0	80.0
	SC	ES/SAF/FAS	VISIT 4	15FEB2016	100/75	76.0	182.0	79.0
	SC	ES/SAF/FAS	VISIT 5	11APR2016	110/75	68.0	182.0	79.0
	SC	ES/SAF/FAS	VISIT 6	27JUN2016	110/60	80.0	182.0	83.0
	SC	ES/SAF/FAS	VISIT 7	09JAN2017	110/70	64.0	182.0	81.0
	SC	ES/SAF/FAS	VISIT 8	08JAN2018	110/70	64.0	182.0	70.0
	SC	ES/SAF/FAS	VISIT 11	11JAN2021	110/70	64.0	182.0	88.0
09/0915	ND basic	ES/SAF/FAS	VISIT 1	05JAN2016	130/80	76.0	182.0	92.0
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	05JAN2016	130/80	76.0	182.0	92.0
	ND basic	ES/SAF/FAS	VISIT 3A	23MAR2016	120/80	60.0	182.0	92.0
	ND basic	ES/SAF/FAS	VISIT 4	02MAY2016	110/80	64.0	182.0	89.0
	ND basic	ES/SAF/FAS	VISIT 5	20JUN2016	115/70	67.0	182.0	89.0
	ND basic	ES/SAF/FAS	VISIT 6	26SEP2016	120/85	64.0	182.0	89.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	21DEC2016	125/80	72.0	182.0	89.0
	ND basic	ES/SAF/FAS	VISIT 7	03APR2017	110/80	88.0	182.0	93.0
	ND basic	ES/SAF/FAS	VISIT 8	09APR2018	120/80	64.0	182.0	94.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	23JUL2020	125/75	80.0	182.0	88.0
	ND basic	ES/SAF/FAS	VISIT 11	22FEB2021	130/80	76.0	182.0	91.0
09/0916	SC	ES/SAF/FAS	VISIT 1	22FEB2016	100/80	80.0	188.0	88.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	22FEB2016	100/80	80.0	188.0	88.0
	SC	ES/SAF/FAS	VISIT 4	06APR2016	110/75	72.0	188.0	88.0
	SC	ES/SAF/FAS	VISIT 5	30MAY2016	110/70	68.0	188.0	88.0
	SC	ES/SAF/FAS	VISIT 6	29AUG2016	110/70	72.0	188.0	88.0
	SC	ES/SAF/FAS	VISIT 7	20FEB2017	110/70	68.0	188.0	88.0
	SC	ES/SAF/FAS	VISIT 8	26FEB2018	130/80	64.0	188.0	88.0
	SC	ES/SAF/FAS	VISIT 11	01MAR2021	120/80	68.0	188.0	88.0
10/1001		ES	VISIT 1	30NOV2015	130/80	88.0	161.0	61.0

ES = Enrolled Set, SAF = Safety Set, FAS = Full Analysis Set
Clinipace: 14DEC21 / 7:42 / l_vs.lst / l_vs.sas

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
10/1001		ES	BASELINE (VISIT 2A)	30NOV2015	130/80	88.0	161.0	61.0
11/1101	ND plus	ES/SAF/FAS	VISIT 1	12JAN2015	110/80	72.0	170.0	65.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	12JAN2015	110/80	72.0	170.0	65.0
	ND plus	ES/SAF/FAS	VISIT 3A	30MAR2015	100/70	64.0	169.0	66.0
	ND plus	ES/SAF/FAS	VISIT 4	11MAY2015	100/75	64.0	169.0	65.0
	ND plus	ES/SAF/FAS	VISIT 5	03JUL2015	110/80	76.0	169.0	65.0
	ND plus	ES/SAF/FAS	VISIT 6	09OCT2015	110/80	68.0	169.0	59.0
	ND plus	ES/SAF/FAS	VISIT 7	08APR2016	110/70	76.0	169.0	66.0
	ND plus	ES/SAF/FAS	VISIT 8	24JAN2017	110/80	80.0	169.0	65.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	27SEP2017	110/70	64.0	170.0	64.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	28JUN2019	-/-	-	170.0	-
	ND plus	ES/SAF/FAS	UNSCHEDULED	30JUL2019	132/91	102.0	169.0	62.0
	ND plus	ES/SAF/FAS	VISIT 11	21APR2020	-/-	-	169.0	-
11/1102	ND basic	ES/SAF/FAS	VISIT 1	15APR2015	140/70	76.0	188.0	75.0
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	20APR2015	120/90	88.0	188.0	75.0
	ND basic	ES/SAF/FAS	VISIT 3A	27JUL2015	130/80	84.0	188.0	76.0
	ND basic	ES/SAF/FAS	VISIT 4	11SEP2015	110/70	72.0	188.0	76.0
	ND basic	ES/SAF/FAS	VISIT 5	23OCT2015	140/90	64.0	188.0	75.0
	ND basic	ES/SAF/FAS	VISIT 6	05FEB2016	120/70	88.0	188.0	75.0
	ND basic	ES/SAF/FAS	VISIT 7	29JUL2016	110/80	72.0	188.0	75.0
	ND basic	ES/SAF/FAS	VISIT 8	14JUL2017	120/70	72.0	188.0	79.0
	ND basic	ES/SAF/FAS	VISIT 11	18AUG2020	110/70	76.0	188.0	78.0
11/1103	SC	ES/SAF/FAS	VISIT 1	30JUL2015	130/100	76.0	166.0	80.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	03AUG2015	140/90	72.0	166.0	80.0
	SC	ES/SAF/FAS	VISIT 4	18SEP2015	130/90	64.0	166.0	81.0
	SC	ES/SAF/FAS	VISIT 5	06NOV2015	125/90	64.0	166.0	79.0
	SC	ES/SAF/FAS	VISIT 6	12FEB2016	110/80	64.0	166.0	78.0
	SC	ES/SAF/FAS	VISIT 7	05AUG2016	115/90	64.0	166.0	81.0
	SC	ES/SAF/FAS	VISIT 8	04AUG2017	120/90	68.0	166.0	85.0
	SC	ES/SAF/FAS	UNSCHEDULED	05JAN2018	130/70	68.0	166.0	85.0
	SC	ES/SAF/FAS	UNSCHEDULED	14FEB2018	135/70	72.0	166.0	85.0
	SC	ES/SAF/FAS	VISIT 11	25AUG2020	135/70	76.0	166.0	88.0
11/1104	ND plus	ES/SAF/FAS	VISIT 1	01MAR2016	160/100	80.0	188.0	96.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	07MAR2016	150/90	84.0	188.0	96.0
	ND plus	ES/SAF/FAS	VISIT 3A	06JUN2016	140/90	72.0	188.0	96.0
	ND plus	ES/SAF/FAS	VISIT 4	22JUL2016	160/90	84.0	188.0	94.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
11/1104	ND plus	ES/SAF/FAS	VISIT 5	09SEP2016	150/90	80.0	188.0	95.0
	ND plus	ES/SAF/FAS	VISIT 6	25NOV2016	140/90	76.0	188.0	94.0
	ND plus	ES/SAF/FAS	VISIT 7	30MAY2017	140/90	84.0	188.0	94.0
	ND plus	ES/SAF/FAS	VISIT 8	12JUN2018	140/100	72.0	188.0	94.0
	ND plus	ES/SAF/FAS	VISIT 11	28MAY2021	150/89	87.0	188.0	102.0
12/1201	ND plus	ES/SAF/FAS	VISIT 1	04SEP2015	120/70	69.0	169.0	77.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	04SEP2015	130/80	68.0	169.0	77.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	22OCT2015	-/-	-	169.0	77.0
	ND plus	ES/SAF/FAS	VISIT 3A	30NOV2015	130/85	66.0	169.0	78.0
	ND plus	ES/SAF/FAS	VISIT 4	08JAN2016	130/80	72.0	169.0	78.0
	ND plus	ES/SAF/FAS	VISIT 5	26FEB2016	125/85	68.0	169.0	78.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	17MAY2016	-/-	-	169.0	-
	ND plus	ES/SAF/FAS	VISIT 6	18MAY2016	120/80	80.0	169.0	78.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	03AUG2016	-/-	-	169.0	-
	ND plus	ES/SAF/FAS	VISIT 7	22NOV2016	120/80	60.0	169.0	78.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	06JUL2017	110/70	71.0	169.0	80.0
	ND plus	ES/SAF/FAS	VISIT 8	21NOV2017	100/75	60.0	169.0	78.0
	ND plus	ES/SAF/FAS	VISIT 11	01DEC2020	125/82	55.0	169.0	80.0
12/1202		ES	VISIT 1	02OCT2015	140/80	-	168.0	78.0
13/1301	ND plus	ES/SAF/FAS	VISIT 1	23APR2015	98/64	72.0	168.0	65.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	26APR2015	98/64	72.0	168.0	65.0
	ND plus	ES/SAF/FAS	VISIT 3A	28JUL2015	110/70	64.0	168.0	64.0
	ND plus	ES/SAF/FAS	VISIT 4	08SEP2015	100/80	60.0	168.0	64.0
	ND plus	ES/SAF/FAS	VISIT 5	22OCT2015	110/80	80.0	168.0	63.0
	ND plus	ES/SAF/FAS	VISIT 6	11JAN2016	120/80	80.0	168.0	63.0
	ND plus	ES/SAF/FAS	VISIT 7	20JUL2016	110/75	72.0	168.0	64.0
	ND plus	ES/SAF/FAS	UNSCHEDULED	22MAR2017	140/70	70.0	168.0	64.0
	ND plus	ES/SAF/FAS	VISIT 8	28JUN2017	120/70	70.0	168.0	63.0
	ND plus	ES/SAF/FAS	VISIT 11	24JUN2020	111/78	80.0	169.0	64.0
13/1302	ND plus	ES/SAF/FAS	VISIT 1	11MAY2015	140/90	75.0	190.0	100.0
	ND plus	ES/SAF/FAS	BASELINE (VISIT 2A)	11MAY2015	160/80	80.0	191.0	100.0
	ND plus	ES/SAF/FAS	VISIT 3A	28JUL2015	130/80	80.0	190.0	99.0
	ND plus	ES/SAF/FAS	VISIT 4	08SEP2015	120/80	80.0	190.0	98.0
	ND plus	ES/SAF/FAS	VISIT 5	22OCT2015	130/80	64.0	190.0	99.0
	ND plus	ES/SAF/FAS	VISIT 6	11JAN2016	130/80	84.0	190.0	97.0
	ND plus	ES/SAF/FAS	VISIT 7	19JUL2016	130/80	74.0	190.0	96.0

Listing 16.2.3.3: Vital signs - all enrolled subjects

Site/ SubjectID	Treatment group	Analysis Set	Visit	Date of evaluation	Blood pressure (systolic/diastolic (mmHg))	Pulse rate (beats/min)	Height (cm)	Weight (kg)
13/1302	ND plus	ES/SAF/FAS	VISIT 8	19JUL2017	130/85	72.0	190.0	100.0
	ND plus	ES/SAF/FAS	VISIT 11	01JUL2020	145/90	110.0	189.0	96.0
13/1303	SC	ES/SAF/FAS	VISIT 1	25JUN2015	130/80	70.0	188.0	72.0
	SC	ES/SAF/FAS	BASELINE (VISIT 2A)	28JUN2015	125/80	74.0	188.0	72.0
	SC	ES/SAF/FAS	VISIT 4	01SEP2015	130/80	62.0	188.0	72.0
	SC	ES/SAF/FAS	VISIT 5	29SEP2015	130/80	80.0	188.0	74.0
	SC	ES/SAF/FAS	VISIT 6	14DEC2015	120/80	80.0	188.0	78.0
	SC	ES/SAF/FAS	VISIT 7	06JUL2016	130/80	80.0	188.0	81.0
	SC	ES/SAF/FAS	VISIT 8	12JUL2017	130/87	72.0	188.0	84.0
	SC	ES/SAF/FAS	UNSCHEDULED	20DEC2017	130/85	72.0	188.0	79.0
	SC	ES/SAF/FAS	VISIT 11	03JUN2020	122/89	93.0	188.0	84.0
	SC	ES/SAF/FAS	UNSCHEDULED	17JUN2020	129/82	75.0	188.0	84.0
13/1304	ND basic	ES/SAF/FAS	VISIT 1	28JUN2015	130/70	70.0	190.0	92.0
	ND basic	ES/SAF/FAS	BASELINE (VISIT 2A)	01JUL2015	120/70	74.0	190.0	92.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	18AUG2015	120/70	70.0	190.0	94.0
	ND basic	ES/SAF/FAS	VISIT 3A	15SEP2015	130/90	76.0	190.0	93.0
	ND basic	ES/SAF/FAS	VISIT 4	02NOV2015	130/80	60.0	190.0	93.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	17NOV2015	120/75	75.0	190.0	92.0
	ND basic	ES/SAF/FAS	VISIT 5	14DEC2015	120/80	80.0	190.0	93.0
	ND basic	ES/SAF/FAS	VISIT 6	01APR2016	120/80	60.0	190.0	93.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	27JUL2016	120/90	82.0	190.0	93.0
	ND basic	ES/SAF/FAS	VISIT 7	14SEP2016	135/90	63.0	190.0	93.0
	ND basic	ES/SAF/FAS	VISIT 8	06SEP2017	125/88	72.0	190.0	94.0
	ND basic	ES/SAF/FAS	UNSCHEDULED	30MAY2018	125/90	68.0	190.0	93.0
	ND basic	ES/SAF/FAS	VISIT 11	02SEP2020	128/84	84.0	190.0	90.0
	ND basic	ES/SAF/FAS	VISIT 11	02SEP2020	128/84	84.0	190.0	90.0
13/1305	ND plus	ES/SAF	VISIT 1	13OCT2015	120/80	80.0	173.0	68.0
	ND plus	ES/SAF	BASELINE (VISIT 2A)	14OCT2015	122/78	80.0	173.0	68.0

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	17OCT2012	16:05	2	Double Read
					VISIT 3A	14JAN2013	16:10	2	Double Read
					VISIT 3K	17JAN2013	16:50	2	Single Read
					VISIT 3L	04FEB2013	16:14	2	Single Read
					VISIT 4	20FEB2013	15:48	2	Double Read
					VISIT 5	17APR2013	15:52	2	Double Read
					VISIT 7	08JAN2014	16:07	2	Double Read
					VISIT 8	16FEB2015	16:15	2	Double Read
					VISIT 11	07MAR2018	15:47	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	17OCT2012	16:05	3	Double Read
					VISIT 3A	14JAN2013	16:10	3	Double Read
					VISIT 3K	17JAN2013	16:50	3	Single Read
					VISIT 3L	04FEB2013	16:14	4	Single Read
					VISIT 4	20FEB2013	15:48	3	Double Read
					VISIT 5	17APR2013	15:52	4	Double Read
					VISIT 7	08JAN2014	16:07	3	Double Read
					VISIT 8	16FEB2015	16:15	3	Double Read
					VISIT 11	07MAR2018	15:47	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	17OCT2012	16:05	2	Double Read
					VISIT 3A	14JAN2013	16:10	2	Double Read
					VISIT 3K	17JAN2013	16:50	2	Single Read
					VISIT 3L	04FEB2013	16:14	2	Single Read
					VISIT 4	20FEB2013	15:48	2	Double Read
					VISIT 5	17APR2013	15:52	2	Double Read
					VISIT 7	08JAN2014	16:07	2	Double Read
					VISIT 8	16FEB2015	16:15	2	Double Read
					VISIT 11	07MAR2018	15:47	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50	N	Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
					VISIT 11	07MAR2018	15:47	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50	N	Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50	N	Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50	N	Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
					VISIT 11	07MAR2018	15:47	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	17OCT2012	16:05	Y	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50	N	Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	Y	Double Read
					VISIT 11	07MAR2018	15:47	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50	N	Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
					VISIT 11	07MAR2018	15:47	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50	N	Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
					VISIT 11	07MAR2018	15:47	N	Double Read
Fracture	4_5		General		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50	N	Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Fracture	4_5		General		VISIT 8	16FEB2015	16:15	N	Double Read
					VISIT 11	07MAR2018	15:47	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	17OCT2012	16:05	16.38	Double Read
					VISIT 3A	14JAN2013	16:10	17.495	Double Read
					VISIT 3K	17JAN2013	16:50	16.20	Single Read
					VISIT 3L	04FEB2013	16:14	16.49	Single Read
					VISIT 4	20FEB2013	15:48	15.845	Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07	17.895	Double Read
					VISIT 8	16FEB2015	16:15	16.38	Double Read
					VISIT 11	07MAR2018	15:47	16.475	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	17OCT2012	16:05	23.41	Double Read
					VISIT 3A	14JAN2013	16:10	16.16	Double Read
					VISIT 3K	17JAN2013	16:50	16.29	Single Read
					VISIT 3L	04FEB2013	16:14	15.68	Single Read
					VISIT 4	20FEB2013	15:48	15.21	Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07	16.475	Double Read
					VISIT 8	16FEB2015	16:15	15.86	Double Read
					VISIT 11	07MAR2018	15:47	15.26	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	17OCT2012	16:05	15.49	Double Read
					VISIT 3A	14JAN2013	16:10	16.27	Double Read
					VISIT 3K	17JAN2013	16:50	14.09	Single Read
					VISIT 3L	04FEB2013	16:14	14.45	Single Read
					VISIT 4	20FEB2013	15:48	14.09	Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07	15.42	Double Read
					VISIT 8	16FEB2015	16:15	13.865	Double Read
					VISIT 11	07MAR2018	15:47	13.585	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	17OCT2012	16:05	13.24575	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	VISIT 3A	14JAN2013	16:10	12.65665	Double Read
					VISIT 3K	17JAN2013	16:50	13.5009	Single Read
					VISIT 3L	04FEB2013	16:14	13.4989	Single Read
					VISIT 4	20FEB2013	15:48	11.85285	Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07	12.07735	Double Read
					VISIT 8	16FEB2015	16:15	11.2502	Double Read
					VISIT 11	07MAR2018	15:47	10.9949	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	17OCT2012	16:05	13.9322	Double Read
					VISIT 3A	14JAN2013	16:10	12.5331	Double Read
					VISIT 3K	17JAN2013	16:50	14.1696	Single Read
					VISIT 3L	04FEB2013	16:14	14.4183	Single Read
					VISIT 4	20FEB2013	15:48	13.75335	Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07	13.67665	Double Read
					VISIT 8	16FEB2015	16:15	11.271655	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	17OCT2012	16:05	12.02275	Double Read
					VISIT 3A	14JAN2013	16:10	12.09885	Double Read
					VISIT 3K	17JAN2013	16:50	12.2075	Single Read
					VISIT 3L	04FEB2013	16:14	11.8246	Single Read
					VISIT 4	20FEB2013	15:48	12.4968	Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07	12.6481	Double Read
					VISIT 8	16FEB2015	16:15	11.4459	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50	N	Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
					VISIT 11	07MAR2018	15:47	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50	N	Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
					VISIT 11	07MAR2018	15:47	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50	N	Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
					VISIT 11	07MAR2018	15:47	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50	N	Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
					VISIT 11	07MAR2018	15:47	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50	N	Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
					VISIT 11	07MAR2018	15:47	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50	N	Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
					VISIT 11	07MAR2018	15:47	N	Double Read
Normal lordotic LS	4_5		General		Baseline	17OCT2012	16:05	Y	Double Read
					VISIT 3A	14JAN2013	16:10	Y	Double Read
					VISIT 3K	17JAN2013	16:50	Y	Single Read
					VISIT 3L	04FEB2013	16:14	Y	Single Read
					VISIT 4	20FEB2013	15:48	Y	Double Read
					VISIT 5	17APR2013	15:52	Y	Double Read
					VISIT 7	08JAN2014	16:07	Y	Double Read
					VISIT 8	16FEB2015	16:15	Y	Double Read
					VISIT 11	07MAR2018	15:47	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	17OCT2012	16:05	0	Double Read
					VISIT 3A	14JAN2013	16:10	0	Double Read
					VISIT 3K	17JAN2013	16:50	0	Single Read
					VISIT 3L	04FEB2013	16:14	0	Single Read
					VISIT 4	20FEB2013	15:48	0	Double Read
					VISIT 5	17APR2013	15:52	0	Double Read
					VISIT 7	08JAN2014	16:07	0	Double Read
					VISIT 8	16FEB2015	16:15	0	Double Read
					VISIT 11	07MAR2018	15:47	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	17OCT2012	16:05	0	Double Read
					VISIT 3A	14JAN2013	16:10	0	Double Read
					VISIT 3K	17JAN2013	16:50	2	Single Read
					VISIT 3L	04FEB2013	16:14	0	Single Read
					VISIT 4	20FEB2013	15:48	2	Double Read
					VISIT 5	17APR2013	15:52	0	Double Read
					VISIT 7	08JAN2014	16:07	2	Double Read
					VISIT 8	16FEB2015	16:15	1	Double Read
					VISIT 11	07MAR2018	15:47	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	17OCT2012	16:05	0	Double Read
					VISIT 3A	14JAN2013	16:10	0	Double Read
					VISIT 3K	17JAN2013	16:50	0	Single Read
					VISIT 3L	04FEB2013	16:14	0	Single Read
					VISIT 4	20FEB2013	15:48	0	Double Read
					VISIT 5	17APR2013	15:52	0	Double Read
					VISIT 7	08JAN2014	16:07	0	Double Read
					VISIT 8	16FEB2015	16:15	0	Double Read
					VISIT 11	07MAR2018	15:47	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50	N	Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
					VISIT 11	07MAR2018	15:47	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50	N	Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
					VISIT 11	07MAR2018	15:47	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50	N	Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
					VISIT 11	07MAR2018	15:47	N	Double Read
Relevant scoliosis	4_5		General		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50	N	Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
					VISIT 11	07MAR2018	15:47	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	17OCT2012	16:05	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50		Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
					VISIT 11	07MAR2018	15:47	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50		Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	17OCT2012	16:05	N	Double Read
					VISIT 3A	14JAN2013	16:10	N	Double Read
					VISIT 3K	17JAN2013	16:50		Single Read
					VISIT 3L	04FEB2013	16:14	N	Single Read
					VISIT 4	20FEB2013	15:48	N	Double Read
					VISIT 5	17APR2013	15:52	N	Double Read
					VISIT 7	08JAN2014	16:07	N	Double Read
					VISIT 8	16FEB2015	16:15	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	90.43552	Single Read
					VISIT 3L	04FEB2013	16:14	112.59104	Single Read
					VISIT 4	20FEB2013	15:48		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	17OCT2012	16:05	83.60688	Double Read
					VISIT 3A	14JAN2013	16:10	91.69136	Double Read
					VISIT 3K	17JAN2013	16:50	86.7696	Single Read
					VISIT 3L	04FEB2013	16:14	88.99936	Single Read
					VISIT 4	20FEB2013	15:48	89.6016	Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07	81.2672	Double Read
					VISIT 8	16FEB2015	16:15	85.36752	Double Read
					VISIT 11	07MAR2018	15:47	82.2432	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	84.6944	Single Read
					VISIT 3L	04FEB2013	16:14	85.65824	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50		Single Read
					VISIT 3L	04FEB2013	16:14		Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	17OCT2012	16:05	80.3104	Double Read
					VISIT 3A	14JAN2013	16:10	81.15696	Double Read
					VISIT 3K	17JAN2013	16:50	79.65728	Single Read
					VISIT 3L	04FEB2013	16:14	82.15744	Single Read
					VISIT 4	20FEB2013	15:48	85.73264	Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07	74.15312	Double Read
					VISIT 8	16FEB2015	16:15	73.4696	Double Read
					VISIT 11	07MAR2018	15:47	74.22848	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50		Single Read
					VISIT 3L	04FEB2013	16:14		Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	113.48832	Single Read
					VISIT 3L	04FEB2013	16:14	103.04	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	17OCT2012	16:05	98.09872	Double Read
					VISIT 3A	14JAN2013	16:10	97.0736	Double Read
					VISIT 3K	17JAN2013	16:50	107.10816	Single Read
					VISIT 3L	04FEB2013	16:14	109.6064	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	VISIT 4	20FEB2013	15:48	100.47824	Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07	94.832	Double Read
					VISIT 8	16FEB2015	16:15	90.82272	Double Read
					VISIT 11	07MAR2018	15:47	90.0984	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	110.40896	Single Read
					VISIT 3L	04FEB2013	16:14	113.84256	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	equal	Single Read
					VISIT 3L	04FEB2013	16:14	equal	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	equal	Single Read
					VISIT 3L	04FEB2013	16:14	higher	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	equal	Single Read
					VISIT 3L	04FEB2013	16:14	equal	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50		Single Read
					VISIT 3L	04FEB2013	16:14	equal	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	17OCT2012	16:05	lower	Double Read
					VISIT 3A	14JAN2013	16:10	lower	Double Read
					VISIT 3K	17JAN2013	16:50	lower	Single Read
					VISIT 3L	04FEB2013	16:14	lower	Single Read
					VISIT 4	20FEB2013	15:48	lower	Double Read
					VISIT 5	17APR2013	15:52	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		VISIT 7	08JAN2014	16:07	lower	Double Read
					VISIT 8	16FEB2015	16:15	lower	Double Read
					VISIT 11	07MAR2018	15:47	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	higher	Single Read
					VISIT 3L	04FEB2013	16:14	higher	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	higher	Single Read
					VISIT 3L	04FEB2013	16:14	higher	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	17OCT2012	16:05	lower	Double Read
					VISIT 3A	14JAN2013	16:10	lower	Double Read
					VISIT 3K	17JAN2013	16:50	lower	Single Read
					VISIT 3L	04FEB2013	16:14	lower	Single Read
					VISIT 4	20FEB2013	15:48	lower	Double Read
					VISIT 5	17APR2013	15:52	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		VISIT 7	08JAN2014	16:07	lower	Double Read
					VISIT 8	16FEB2015	16:15	lower	Double Read
					VISIT 11	07MAR2018	15:47	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	higher	Single Read
					VISIT 3L	04FEB2013	16:14	equal	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	equal	Single Read
					VISIT 3L	04FEB2013	16:14	equal	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	equal	Single Read
					VISIT 3L	04FEB2013	16:14	higher	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 11	07MAR2018	15:47		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	equal	Single Read
					VISIT 3L	04FEB2013	16:14	equal	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	4.6979989808	Single Read
					VISIT 3L	04FEB2013	16:14	29.364226261	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	17OCT2012	16:05	10.288642772	Double Read
					VISIT 3A	14JAN2013	16:10	15.348598607	Double Read
					VISIT 3K	17JAN2013	16:50	7.0211245116	Single Read
					VISIT 3L	04FEB2013	16:14	10.832587056	Single Read
					VISIT 4	20FEB2013	15:48	5.6888398165	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07	12.2507626975	Double Read
					VISIT 8	16FEB2015	16:15	8.63484287413	Double Read
					VISIT 11	07MAR2018	15:47	7.1156989978	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	9.78427042636	Single Read
					VISIT 3L	04FEB2013	16:14	14.4385935111	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50		Single Read
					VISIT 3L	04FEB2013	16:14		Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	17OCT2012	16:05	9.83505350771	Double Read
					VISIT 3A	14JAN2013	16:10	10.3354509937	Double Read
					VISIT 3K	17JAN2013	16:50	8.11149991507	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3L	04FEB2013	16:14	8.90096823509	Single Read
					VISIT 4	20FEB2013	15:48	4.65655851878	Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07	11.9677187023	Double Read
					VISIT 8	16FEB2015	16:15	11.2801087141	Double Read
					VISIT 11	07MAR2018	15:47	8.41607609986	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50		Single Read
					VISIT 3L	04FEB2013	16:14		Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	33.0906743672	Single Read
					VISIT 3L	04FEB2013	16:14	1.63799558349	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	17OCT2012	16:05	10.8430983523	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	VISIT 3A	14JAN2013	16:10	4.0667912349	Double Read
					VISIT 3K	17JAN2013	16:50	2 4.4731374214	Single Read
					VISIT 3L	04FEB2013	16:14	4 12.739935451	Single Read
					VISIT 4	20FEB2013	15:48	5 9.9767827416	Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07	1 17.678206217	Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47	9 18.458773568	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	3 15.401121114	Single Read
					VISIT 3L	04FEB2013	16:14	4 8.1535586886	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	11032	Single Read
					VISIT 3L	04FEB2013	16:14	11546	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	17OCT2012	16:05	16711.0	Double Read
					VISIT 3A	14JAN2013	16:10	16925.5	Double Read
					VISIT 3K	17JAN2013	16:50	16997	Single Read
					VISIT 3L	04FEB2013	16:14	16453	Single Read
					VISIT 4	20FEB2013	15:48	16354.5	Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07	17053.5	Double Read
					VISIT 8	16FEB2015	16:15	15549.5	Double Read
					VISIT 11	07MAR2018	15:47	15582.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	5965	Single Read
					VISIT 3L	04FEB2013	16:14	4907	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50		Single Read
					VISIT 3L	04FEB2013	16:14		Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	17OCT2012	16:05	20467.0	Double Read
					VISIT 3A	14JAN2013	16:10	20944.5	Double Read
					VISIT 3K	17JAN2013	16:50		Single Read
					VISIT 3L	04FEB2013	16:14	20005	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 4	20FEB2013	15:48	20122.5	Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07	20667.0	Double Read
					VISIT 8	16FEB2015	16:15	19788.5	Double Read
					VISIT 11	07MAR2018	15:47	18566.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50		Single Read
					VISIT 3L	04FEB2013	16:14		Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50		Single Read
					VISIT 3L	04FEB2013	16:14	13074	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	17OCT2012	16:05	19720.5	Double Read
					VISIT 3A	14JAN2013	16:10	20377.0	Double Read
					VISIT 3K	17JAN2013	16:50		Single Read
					VISIT 3L	04FEB2013	16:14	18832	Single Read
					VISIT 4	20FEB2013	15:48	19108.0	Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07	19987.0	Double Read
					VISIT 8	16FEB2015	16:15	18064.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0103 Age=52 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	VISIT 11	07MAR2018	15:47	18698.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	17OCT2012	16:05		Double Read
					VISIT 3A	14JAN2013	16:10		Double Read
					VISIT 3K	17JAN2013	16:50	6780	Single Read
					VISIT 3L	04FEB2013	16:14	5758	Single Read
					VISIT 4	20FEB2013	15:48		Double Read
					VISIT 5	17APR2013	15:52		Double Read
					VISIT 7	08JAN2014	16:07		Double Read
					VISIT 8	16FEB2015	16:15		Double Read
					VISIT 11	07MAR2018	15:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S	4_5	Central Disc		Baseline	22OCT2012	15:52	3	Double Read
					VISIT 3A	21JAN2013	16:12	3	Double Read
					VISIT 3K	24JAN2013	16:26	4	Single Read
					VISIT 3L	13FEB2013	16:44	4	Single Read
					VISIT 4	27FEB2013	16:07	3	Double Read
					VISIT 5	26APR2013	15:49	3	Double Read
					VISIT 6	31JUL2013	16:50	4	Double Read
					VISIT 7	15JAN2014	16:47	3	Double Read
					VISIT 8	23JUN2015	16:11	3	Double Read
					VISIT 11	24JAN2018	16:11	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22OCT2012	15:52	3	Double Read
					VISIT 3A	21JAN2013	16:12	3	Double Read
					VISIT 3K	24JAN2013	16:26	4	Single Read
					VISIT 3L	13FEB2013	16:44	4	Single Read
					VISIT 4	27FEB2013	16:07	3	Double Read
					VISIT 5	26APR2013	15:49	3	Double Read
					VISIT 6	31JUL2013	16:50	3	Double Read
					VISIT 7	15JAN2014	16:47	3	Double Read
					VISIT 8	23JUN2015	16:11	3	Double Read
					VISIT 11	24JAN2018	16:11	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22OCT2012	15:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S	4_5	Caudal Disc		VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S	4_5	Central Disc		Baseline	22OCT2012	15:52	N	Double Read
					VISIT 3A	21JAN2013	16:12	N	Double Read
					VISIT 3K	24JAN2013	16:26	N	Single Read
					VISIT 3L	13FEB2013	16:44	N	Single Read
					VISIT 4	27FEB2013	16:07	N	Double Read
					VISIT 5	26APR2013	15:49	N	Double Read
					VISIT 6	31JUL2013	16:50	N	Double Read
					VISIT 7	15JAN2014	16:47	N	Double Read
					VISIT 8	23JUN2015	16:11	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 11	24JAN2018	16:11	N	Double Read
					Baseline	22OCT2012	15:52	N	Double Read
					VISIT 3A	21JAN2013	16:12	N	Double Read
					VISIT 3K	24JAN2013	16:26	N	Single Read
					VISIT 3L	13FEB2013	16:44	N	Single Read
					VISIT 4	27FEB2013	16:07	N	Double Read
					VISIT 5	26APR2013	15:49	N	Double Read
					VISIT 6	31JUL2013	16:50	N	Double Read
					VISIT 7	15JAN2014	16:47	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S	4_5	Caudal Disc		VISIT 8	23JUN2015	16:11	N	Double Read
					VISIT 11	24JAN2018	16:11	Y	Double Read
					Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Caudal Disc)	5_S	4_5	Caudal Disc		VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
Dorsal disc extrusion (Central Disc)	5_S	4_5	Central Disc		Baseline	22OCT2012	15:52	Y	Double Read
					VISIT 3A	21JAN2013	16:12	N	Double Read
					VISIT 3K	24JAN2013	16:26	Y	Single Read
					VISIT 3L	13FEB2013	16:44	Y	Single Read
					VISIT 4	27FEB2013	16:07	N	Double Read
					VISIT 5	26APR2013	15:49	Y	Double Read
					VISIT 6	31JUL2013	16:50	N	Double Read
					VISIT 7	15JAN2014	16:47	N	Double Read
					VISIT 8	23JUN2015	16:11	Y	Double Read
					VISIT 11	24JAN2018	16:11	N	Double Read
Dorsal disc extrusion (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22OCT2012	15:52	N	Double Read
					VISIT 3A	21JAN2013	16:12	N	Double Read
					VISIT 3K	24JAN2013	16:26	Y	Single Read
					VISIT 3L	13FEB2013	16:44	Y	Single Read
					VISIT 4	27FEB2013	16:07	N	Double Read
					VISIT 5	26APR2013	15:49	N	Double Read
					VISIT 6	31JUL2013	16:50	Y	Double Read
					VISIT 7	15JAN2014	16:47	Y	Double Read
					VISIT 8	23JUN2015	16:11	Y	Double Read
					VISIT 11	24JAN2018	16:11	N	Double Read
Extradiscal fluid collection	5_S	4_5	General		Baseline	22OCT2012	15:52	N	Double Read
					VISIT 3A	21JAN2013	16:12	N	Double Read
					VISIT 3K	24JAN2013	16:26	N	Single Read
					VISIT 3L	13FEB2013	16:44	N	Single Read
					VISIT 4	27FEB2013	16:07	N	Double Read
					VISIT 5	26APR2013	15:49	N	Double Read
					VISIT 6	31JUL2013	16:50	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S	4_5	General		VISIT 7	15JAN2014	16:47	N	Double Read
					VISIT 8	23JUN2015	16:11	N	Double Read
					VISIT 11	24JAN2018	16:11	N	Double Read
Fracture	5_S	4_5	General		Baseline	22OCT2012	15:52	N	Double Read
					VISIT 3A	21JAN2013	16:12	N	Double Read
					VISIT 3K	24JAN2013	16:26	N	Single Read
					VISIT 3L	13FEB2013	16:44	N	Single Read
					VISIT 4	27FEB2013	16:07	N	Double Read
					VISIT 5	26APR2013	15:49	N	Double Read
					VISIT 6	31JUL2013	16:50	N	Double Read
					VISIT 7	15JAN2014	16:47	N	Double Read
					VISIT 8	23JUN2015	16:11	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	22OCT2012	15:52	14.3	Double Read
					VISIT 3A	21JAN2013	16:12	15.125	Double Read
					VISIT 3K	24JAN2013	16:26	11.96	Single Read
					VISIT 3L	13FEB2013	16:44	13.31	Single Read
					VISIT 4	27FEB2013	16:07	14.485	Double Read
					VISIT 5	26APR2013	15:49	14.33	Double Read
					VISIT 6	31JUL2013	16:50	13.23	Double Read
					VISIT 7	15JAN2014	16:47	12.875	Double Read
					VISIT 8	23JUN2015	16:11	11.9	Double Read
					VISIT 11	24JAN2018	16:11	10.97	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	22OCT2012	15:52	16.62	Double Read
					VISIT 3A	21JAN2013	16:12	16.595	Double Read
					VISIT 3K	24JAN2013	16:26	16.01	Single Read
					VISIT 3L	13FEB2013	16:44	15.83	Single Read
					VISIT 4	27FEB2013	16:07	16.15	Double Read
					VISIT 5	26APR2013	15:49	16.985	Double Read
					VISIT 6	31JUL2013	16:50	15.055	Double Read
					VISIT 7	15JAN2014	16:47	15.545	Double Read
					VISIT 8	23JUN2015	16:11	14.44	Double Read
					VISIT 11	24JAN2018	16:11	14.005	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	22OCT2012	15:52	8.4249	Double Read
					VISIT 3A	21JAN2013	16:12	9.31229	Double Read
					VISIT 3K	24JAN2013	16:26	9.62975	Single Read
					VISIT 3L	13FEB2013	16:44	9.91964	Single Read
					VISIT 4	27FEB2013	16:07	8.653945	Double Read
					VISIT 5	26APR2013	15:49	9.12573	Double Read
					VISIT 6	31JUL2013	16:50	7.57327	Double Read
					VISIT 7	15JAN2014	16:47	8.42061	Double Read
					VISIT 8	23JUN2015	16:11	7.413425	Double Read
					VISIT 11	24JAN2018	16:11	5.8958	Double Read
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	22OCT2012	15:52	11.62305	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	VISIT 3A	21JAN2013	16:12	11.29565	Double Read
					VISIT 3K	24JAN2013	16:26	12.4159	Single Read
					VISIT 3L	13FEB2013	16:44	11.9673	Single Read
					VISIT 4	27FEB2013	16:07	11.83995	Double Read
					VISIT 5	26APR2013	15:49	12.02895	Double Read
					VISIT 6	31JUL2013	16:50	11.0845	Double Read
					VISIT 7	15JAN2014	16:47	10.1658	Double Read
					VISIT 8	23JUN2015	16:11	10.426065	Double Read
					VISIT 11	24JAN2018	16:11	9.412845	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S	4_5	Central Disc		Baseline	22OCT2012	15:52	N	Double Read
					VISIT 3A	21JAN2013	16:12	N	Double Read
					VISIT 3K	24JAN2013	16:26	N	Single Read
					VISIT 3L	13FEB2013	16:44	N	Single Read
					VISIT 4	27FEB2013	16:07	N	Double Read
					VISIT 5	26APR2013	15:49	N	Double Read
					VISIT 6	31JUL2013	16:50	N	Double Read
					VISIT 7	15JAN2014	16:47	N	Double Read
					VISIT 8	23JUN2015	16:11	N	Double Read
					VISIT 11	24JAN2018	16:11	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22OCT2012	15:52	N	Double Read
					VISIT 3A	21JAN2013	16:12	N	Double Read
					VISIT 3K	24JAN2013	16:26	N	Single Read
					VISIT 3L	13FEB2013	16:44	N	Single Read
					VISIT 4	27FEB2013	16:07	N	Double Read
					VISIT 5	26APR2013	15:49	N	Double Read
					VISIT 6	31JUL2013	16:50	N	Double Read
					VISIT 7	15JAN2014	16:47	N	Double Read
					VISIT 8	23JUN2015	16:11	N	Double Read
					VISIT 11	24JAN2018	16:11	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S	4_5	Central Disc		Baseline	22OCT2012	15:52	N	Double Read
					VISIT 3A	21JAN2013	16:12	N	Double Read
					VISIT 3K	24JAN2013	16:26	N	Single Read
					VISIT 3L	13FEB2013	16:44	N	Single Read
					VISIT 4	27FEB2013	16:07	N	Double Read
					VISIT 5	26APR2013	15:49	N	Double Read
					VISIT 6	31JUL2013	16:50	N	Double Read
					VISIT 7	15JAN2014	16:47	N	Double Read
					VISIT 8	23JUN2015	16:11	N	Double Read
					VISIT 11	24JAN2018	16:11	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22OCT2012	15:52	N	Double Read
					VISIT 3A	21JAN2013	16:12	N	Double Read
					VISIT 3K	24JAN2013	16:26	N	Single Read
					VISIT 3L	13FEB2013	16:44	N	Single Read
					VISIT 4	27FEB2013	16:07	N	Double Read
					VISIT 5	26APR2013	15:49	N	Double Read
					VISIT 6	31JUL2013	16:50	N	Double Read
					VISIT 7	15JAN2014	16:47	N	Double Read
					VISIT 8	23JUN2015	16:11	N	Double Read
					VISIT 11	24JAN2018	16:11	N	Double Read
Normal lordotic LS	5_S	4_5	General		Baseline	22OCT2012	15:52	Y	Double Read
					VISIT 3A	21JAN2013	16:12	Y	Double Read
					VISIT 3K	24JAN2013	16:26	Y	Single Read
					VISIT 3L	13FEB2013	16:44	Y	Single Read
					VISIT 4	27FEB2013	16:07	Y	Double Read
					VISIT 5	26APR2013	15:49	Y	Double Read
					VISIT 6	31JUL2013	16:50	Y	Double Read
					VISIT 7	15JAN2014	16:47	Y	Double Read
					VISIT 8	23JUN2015	16:11	Y	Double Read
					VISIT 11	24JAN2018	16:11	N	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S	4_5	Central Disc		Baseline	22OCT2012	15:52	0	Double Read
					VISIT 3A	21JAN2013	16:12	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S	4_5	Central Disc		VISIT 3K	24JAN2013	16:26	2	Single Read
					VISIT 3L	13FEB2013	16:44	2	Single Read
					VISIT 4	27FEB2013	16:07	0	Double Read
					VISIT 5	26APR2013	15:49	0	Double Read
					VISIT 6	31JUL2013	16:50	0	Double Read
					VISIT 7	15JAN2014	16:47	0	Double Read
					VISIT 8	23JUN2015	16:11	2	Double Read
					VISIT 11	24JAN2018	16:11	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22OCT2012	15:52	0	Double Read
					VISIT 3A	21JAN2013	16:12	0	Double Read
					VISIT 3K	24JAN2013	16:26	0	Single Read
					VISIT 3L	13FEB2013	16:44	0	Single Read
					VISIT 4	27FEB2013	16:07	0	Double Read
					VISIT 5	26APR2013	15:49	0	Double Read
					VISIT 6	31JUL2013	16:50	0	Double Read
					VISIT 7	15JAN2014	16:47	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S	4_5	Caudal Disc		VISIT 8	23JUN2015	16:11	0	Double Read
					VISIT 11	24JAN2018	16:11	0	Double Read
					Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49	N	Double Read
Protruding osteophyte (Central Disc)	5_S	4_5	Central Disc		VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
					Baseline	22OCT2012	15:52	N	Double Read
					VISIT 3A	21JAN2013	16:12	N	Double Read
					VISIT 3K	24JAN2013	16:26	N	Single Read
					VISIT 3L	13FEB2013	16:44	N	Single Read
					VISIT 4	27FEB2013	16:07	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S	4_5	Central Disc		VISIT 5	26APR2013	15:49	N	Double Read
					VISIT 6	31JUL2013	16:50	N	Double Read
					VISIT 7	15JAN2014	16:47	N	Double Read
					VISIT 8	23JUN2015	16:11	N	Double Read
					VISIT 11	24JAN2018	16:11	N	Double Read
Protruding osteophyte (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22OCT2012	15:52	N	Double Read
					VISIT 3A	21JAN2013	16:12	N	Double Read
					VISIT 3K	24JAN2013	16:26	N	Single Read
					VISIT 3L	13FEB2013	16:44	N	Single Read
					VISIT 4	27FEB2013	16:07	N	Double Read
					VISIT 5	26APR2013	15:49	N	Double Read
					VISIT 6	31JUL2013	16:50	N	Double Read
					VISIT 7	15JAN2014	16:47	N	Double Read
					VISIT 8	23JUN2015	16:11	N	Double Read
					VISIT 11	24JAN2018	16:11	N	Double Read
Relevant scoliosis	5_S	4_5	General		Baseline	22OCT2012	15:52	N	Double Read
					VISIT 3A	21JAN2013	16:12	N	Double Read
					VISIT 3K	24JAN2013	16:26	N	Single Read
					VISIT 3L	13FEB2013	16:44	N	Single Read
					VISIT 4	27FEB2013	16:07	N	Double Read
					VISIT 5	26APR2013	15:49	N	Double Read
					VISIT 6	31JUL2013	16:50	N	Double Read
					VISIT 7	15JAN2014	16:47	N	Double Read
					VISIT 8	23JUN2015	16:11	N	Double Read
					VISIT 11	24JAN2018	16:11	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S	4_5	Caudal Disc		VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S	4_5	Central Disc		Baseline	22OCT2012	15:52	N	Double Read
					VISIT 3A	21JAN2013	16:12	N	Double Read
					VISIT 3K	24JAN2013	16:26	N	Single Read
					VISIT 3L	13FEB2013	16:44	N	Single Read
					VISIT 4	27FEB2013	16:07	N	Double Read
					VISIT 5	26APR2013	15:49	N	Double Read
					VISIT 6	31JUL2013	16:50	N	Double Read
					VISIT 7	15JAN2014	16:47	N	Double Read
					VISIT 8	23JUN2015	16:11	N	Double Read
					VISIT 11	24JAN2018	16:11	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22OCT2012	15:52	N	Double Read
					VISIT 3A	21JAN2013	16:12	N	Double Read
					VISIT 3K	24JAN2013	16:26	N	Single Read
					VISIT 3L	13FEB2013	16:44	N	Single Read
					VISIT 4	27FEB2013	16:07	N	Double Read
					VISIT 5	26APR2013	15:49	N	Double Read
					VISIT 6	31JUL2013	16:50	N	Double Read
					VISIT 7	15JAN2014	16:47	N	Double Read
					VISIT 8	23JUN2015	16:11	N	Double Read
					VISIT 11	24JAN2018	16:11	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	VISIT 11	24JAN2018	16:11		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	22OCT2012	15:52	87.2136	Double Read
					VISIT 3A	21JAN2013	16:12	76.29664	Double Read
					VISIT 3K	24JAN2013	16:26	77.80992	Single Read
					VISIT 3L	13FEB2013	16:44	82.6896	Single Read
					VISIT 4	27FEB2013	16:07	90.2976	Double Read
					VISIT 5	26APR2013	15:49	81.58048	Double Read
					VISIT 6	31JUL2013	16:50	81.88528	Double Read
					VISIT 7	15JAN2014	16:47	69.57824	Double Read
					VISIT 8	23JUN2015	16:11	77.27728	Double Read
					VISIT 11	24JAN2018	16:11	85.34464	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
T2 (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
T2 (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	22OCT2012	15:52	76.82544	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	VISIT 3A	21JAN2013	16:12	78.85296	Double Read
					VISIT 3K	24JAN2013	16:26	74.4704	Single Read
					VISIT 3L	13FEB2013	16:44	77.4544	Single Read
					VISIT 4	27FEB2013	16:07	80.67296	Double Read
					VISIT 5	26APR2013	15:49	83.04224	Double Read
					VISIT 6	31JUL2013	16:50	83.59328	Double Read
					VISIT 7	15JAN2014	16:47	70.21744	Double Read
					VISIT 8	23JUN2015	16:11	70.94768	Double Read
					VISIT 11	24JAN2018	16:11	92.38624	Double Read
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S	4_5	Central Disc		Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26	equal	Single Read
					VISIT 3L	13FEB2013	16:44	equal	Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26	equal	Single Read
					VISIT 3L	13FEB2013	16:44	equal	Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26	equal	Single Read
					VISIT 3L	13FEB2013	16:44	equal	Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	22OCT2012	15:52	equal	Double Read
					VISIT 3A	21JAN2013	16:12	equal	Double Read
					VISIT 3K	24JAN2013	16:26	equal	Single Read
					VISIT 3L	13FEB2013	16:44	equal	Single Read
					VISIT 4	27FEB2013	16:07	lower	Double Read
					VISIT 5	26APR2013	15:49	lower	Double Read
					VISIT 6	31JUL2013	16:50	lower	Double Read
					VISIT 7	15JAN2014	16:47	lower	Double Read
					VISIT 8	23JUN2015	16:11	equal	Double Read
					VISIT 11	24JAN2018	16:11	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	22OCT2012	15:52	equal	Double Read
					VISIT 3A	21JAN2013	16:12	equal	Double Read
					VISIT 3K	24JAN2013	16:26	equal	Single Read
					VISIT 3L	13FEB2013	16:44	equal	Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49	equal	Double Read
					VISIT 6	31JUL2013	16:50	equal	Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11	higher	Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S	4_5	Central Disc		Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26	equal	Single Read
					VISIT 3L	13FEB2013	16:44	equal	Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26	equal	Single Read
					VISIT 3L	13FEB2013	16:44	equal	Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	22OCT2012	15:52	9.63533888228	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	VISIT 3A	21JAN2013	16:12	7.46959741804	Double Read
					VISIT 3K	24JAN2013	16:26	5.80156956005	Single Read
					VISIT 3L	13FEB2013	16:44	3.27652114829	Single Read
					VISIT 4	27FEB2013	16:07	7.19098352301	Double Read
					VISIT 5	26APR2013	15:49	5.93460845931	Double Read
					VISIT 6	31JUL2013	16:50	6.27860030575	Double Read
					VISIT 7	15JAN2014	16:47	7.98188551045	Double Read
					VISIT 8 VISIT 11	23JUN2015 24JAN2018	16:11 16:11	7.8332393409 10.5090334635	Double Read Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7 VISIT 8 VISIT 11	15JAN2014 23JUN2015 24JAN2018	16:47 16:11 16:11		Double Read Double Read Double Read
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5 VISIT 6	26APR2013 31JUL2013	15:49 16:50		Double Read Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	22OCT2012	15:52	7.1398946832	Double Read
					VISIT 3A	21JAN2013	16:12	7.1691116018	Double Read
					VISIT 3K	24JAN2013	16:26	8.4026906743	Single Read
					VISIT 3L	13FEB2013	16:44	9.3426193307	Single Read
					VISIT 4	27FEB2013	16:07	7.7005877356	Double Read
					VISIT 5	26APR2013	15:49	9.9254560897	Double Read
					VISIT 6	31JUL2013	16:50	9.1646611177	Double Read
					VISIT 7	15JAN2014	16:47	11.853541702	Double Read
					VISIT 8	23JUN2015	16:11	11.325999660	Double Read
					VISIT 11	24JAN2018	16:11	2.2611992525	Double Read
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	22OCT2012	15:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	22OCT2012	15:52	12894.5	Double Read
					VISIT 3A	21JAN2013	16:12	13740.5	Double Read
					VISIT 3K	24JAN2013	16:26	13664	Single Read
					VISIT 3L	13FEB2013	16:44	14428	Single Read
					VISIT 4	27FEB2013	16:07	14081.0	Double Read
					VISIT 5	26APR2013	15:49	14091.0	Double Read
					VISIT 6	31JUL2013	16:50	14344.0	Double Read
					VISIT 7	15JAN2014	16:47	12996.0	Double Read
					VISIT 8	23JUN2015	16:11	12866.0	Double Read
					VISIT 11	24JAN2018	16:11	10960.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0104 Age=31 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read
Volume (mm ³) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	22OCT2012	15:52	21969.0	Double Read
					VISIT 3A	21JAN2013	16:12	23509.5	Double Read
					VISIT 3K	24JAN2013	16:26	22482	Single Read
					VISIT 3L	13FEB2013	16:44	20606	Single Read
					VISIT 4	27FEB2013	16:07	21808.5	Double Read
					VISIT 5	26APR2013	15:49	21228.5	Double Read
					VISIT 6	31JUL2013	16:50	19944.0	Double Read
					VISIT 7	15JAN2014	16:47	20493.5	Double Read
					VISIT 8	23JUN2015	16:11	20254.5	Double Read
					VISIT 11	24JAN2018	16:11	16865.5	Double Read
Volume (mm ³) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	22OCT2012	15:52		Double Read
					VISIT 3A	21JAN2013	16:12		Double Read
					VISIT 3K	24JAN2013	16:26		Single Read
					VISIT 3L	13FEB2013	16:44		Single Read
					VISIT 4	27FEB2013	16:07		Double Read
					VISIT 5	26APR2013	15:49		Double Read
					VISIT 6	31JUL2013	16:50		Double Read
					VISIT 7	15JAN2014	16:47		Double Read
					VISIT 8	23JUN2015	16:11		Double Read
					VISIT 11	24JAN2018	16:11		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	27NOV2012	19:55	3	Double Read
					VISIT 3A	18FEB2013	16:11	3	Double Read
					VISIT 3K	25FEB2013	16:21	4	Single Read
					VISIT 3L	12MAR2013	16:29	4	Single Read
					VISIT 4	03APR2013	15:56	3	Double Read
					VISIT 5	22MAY2013	16:13	4	Double Read
					VISIT 6	21AUG2013	15:55	4	Double Read
					VISIT 7	19FEB2014	16:12	3	Double Read
					VISIT 8	18FEB2015	15:43	4	Double Read
					VISIT 11	14FEB2018	16:29	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27NOV2012	19:55	2	Double Read
					VISIT 3A	18FEB2013	16:11	2	Double Read
					VISIT 3K	25FEB2013	16:21	2	Single Read
					VISIT 3L	12MAR2013	16:29	2	Single Read
					VISIT 4	03APR2013	15:56	2	Double Read
					VISIT 5	22MAY2013	16:13	2	Double Read
					VISIT 6	21AUG2013	15:55	2	Double Read
					VISIT 7	19FEB2014	16:12	2	Double Read
					VISIT 8	18FEB2015	15:43	2	Double Read
					VISIT 11	14FEB2018	16:29	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	27NOV2012	19:55		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	27NOV2012	19:55	N	Double Read
					VISIT 3A	18FEB2013	16:11	N	Double Read
					VISIT 3K	25FEB2013	16:21	N	Single Read
					VISIT 3L	12MAR2013	16:29	N	Single Read
					VISIT 4	03APR2013	15:56	N	Double Read
					VISIT 5	22MAY2013	16:13	N	Double Read
					VISIT 6	21AUG2013	15:55	N	Double Read
					VISIT 7	19FEB2014	16:12	N	Double Read
					VISIT 8	18FEB2015	15:43	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27NOV2012	19:55	N	Double Read
					VISIT 3A	18FEB2013	16:11	N	Double Read
					VISIT 3K	25FEB2013	16:21	N	Single Read
					VISIT 3L	12MAR2013	16:29	N	Single Read
					VISIT 4	03APR2013	15:56	N	Double Read
					VISIT 5	22MAY2013	16:13	N	Double Read
					VISIT 6	21AUG2013	15:55	N	Double Read
					VISIT 7	19FEB2014	16:12	N	Double Read
					VISIT 8	18FEB2015	15:43	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	27NOV2012	19:55	Y	Double Read
					VISIT 3A	18FEB2013	16:11	Y	Double Read
					VISIT 3K	25FEB2013	16:21	Y	Single Read
					VISIT 3L	12MAR2013	16:29	Y	Single Read
					VISIT 4	03APR2013	15:56	Y	Double Read
					VISIT 5	22MAY2013	16:13	Y	Double Read
					VISIT 6	21AUG2013	15:55	Y	Double Read
					VISIT 7	19FEB2014	16:12	Y	Double Read
					VISIT 8	18FEB2015	15:43	Y	Double Read
					VISIT 11	14FEB2018	16:29	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27NOV2012	19:55	N	Double Read
					VISIT 3A	18FEB2013	16:11	N	Double Read
					VISIT 3K	25FEB2013	16:21	N	Single Read
					VISIT 3L	12MAR2013	16:29	N	Single Read
					VISIT 4	03APR2013	15:56	N	Double Read
					VISIT 5	22MAY2013	16:13	N	Double Read
					VISIT 6	21AUG2013	15:55	N	Double Read
					VISIT 7	19FEB2014	16:12	N	Double Read
					VISIT 8	18FEB2015	15:43	N	Double Read
					VISIT 11	14FEB2018	16:29	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	27NOV2012	19:55	N	Double Read
					VISIT 3A	18FEB2013	16:11	N	Double Read
					VISIT 3K	25FEB2013	16:21	N	Single Read
					VISIT 3L	12MAR2013	16:29	N	Single Read
					VISIT 4	03APR2013	15:56	N	Double Read
					VISIT 5	22MAY2013	16:13	N	Double Read
					VISIT 6	21AUG2013	15:55	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 7	19FEB2014	16:12	N	Double Read
					VISIT 8	18FEB2015	15:43	N	Double Read
					VISIT 11	14FEB2018	16:29	N	Double Read
Fracture	5_S		General		Baseline	27NOV2012	19:55	N	Double Read
					VISIT 3A	18FEB2013	16:11	N	Double Read
					VISIT 3K	25FEB2013	16:21	N	Single Read
					VISIT 3L	12MAR2013	16:29	N	Single Read
					VISIT 4	03APR2013	15:56	N	Double Read
					VISIT 5	22MAY2013	16:13	N	Double Read
					VISIT 6	21AUG2013	15:55	N	Double Read
					VISIT 7	19FEB2014	16:12	N	Double Read
					VISIT 8	18FEB2015	15:43	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	27NOV2012	19:55	17.295	Double Read
					VISIT 3A	18FEB2013	16:11	16.9	Double Read
					VISIT 3K	25FEB2013	16:21	18.10	Single Read
					VISIT 3L	12MAR2013	16:29	17.18	Single Read
					VISIT 4	03APR2013	15:56	17.58	Double Read
					VISIT 5	22MAY2013	16:13	16.9	Double Read
					VISIT 6	21AUG2013	15:55	15.045	Double Read
					VISIT 7	19FEB2014	16:12	15.19	Double Read
					VISIT 8	18FEB2015	15:43	16.315	Double Read
					VISIT 11	14FEB2018	16:29	14.91	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	27NOV2012	19:55	18.46	Double Read
					VISIT 3A	18FEB2013	16:11	18.26	Double Read
					VISIT 3K	25FEB2013	16:21	18.28	Single Read
					VISIT 3L	12MAR2013	16:29	18.02	Single Read
					VISIT 4	03APR2013	15:56	18.405	Double Read
					VISIT 5	22MAY2013	16:13	18.415	Double Read
					VISIT 6	21AUG2013	15:55	17.67	Double Read
					VISIT 7	19FEB2014	16:12	16.475	Double Read
					VISIT 8	18FEB2015	15:43	18.18	Double Read
					VISIT 11	14FEB2018	16:29	16.795	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	27NOV2012	19:55	11.26245	Double Read
					VISIT 3A	18FEB2013	16:11	10.08365	Double Read
					VISIT 3K	25FEB2013	16:21	11.1608	Single Read
					VISIT 3L	12MAR2013	16:29	11.3933	Single Read
					VISIT 4	03APR2013	15:56	11.2408	Double Read
					VISIT 5	22MAY2013	16:13	10.26772	Double Read
					VISIT 6	21AUG2013	15:55	10.4415	Double Read
					VISIT 7	19FEB2014	16:12	9.586685	Double Read
					VISIT 8	18FEB2015	15:43	9.440105	Double Read
					VISIT 11	14FEB2018	16:29	8.77199	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	27NOV2012	19:55	15.444	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 3A	18FEB2013	16:11	15.7137	Double Read
					VISIT 3K	25FEB2013	16:21	15.6222	Single Read
					VISIT 3L	12MAR2013	16:29	16.0096	Single Read
					VISIT 4	03APR2013	15:56	15.01995	Double Read
					VISIT 5	22MAY2013	16:13	15.8686	Double Read
					VISIT 6	21AUG2013	15:55	15.6567	Double Read
					VISIT 7	19FEB2014	16:12	14.79215	Double Read
					VISIT 8	18FEB2015	15:43	15.0777	Double Read
					VISIT 11	14FEB2018	16:29	15.20215	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	27NOV2012	19:55	N	Double Read
					VISIT 3A	18FEB2013	16:11	N	Double Read
					VISIT 3K	25FEB2013	16:21	N	Single Read
					VISIT 3L	12MAR2013	16:29	N	Single Read
					VISIT 4	03APR2013	15:56	N	Double Read
					VISIT 5	22MAY2013	16:13	N	Double Read
					VISIT 6	21AUG2013	15:55	N	Double Read
					VISIT 7	19FEB2014	16:12	N	Double Read
					VISIT 8	18FEB2015	15:43	N	Double Read
					VISIT 11	14FEB2018	16:29	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27NOV2012	19:55	N	Double Read
					VISIT 3A	18FEB2013	16:11	N	Double Read
					VISIT 3K	25FEB2013	16:21	N	Single Read
					VISIT 3L	12MAR2013	16:29	N	Single Read
					VISIT 4	03APR2013	15:56	N	Double Read
					VISIT 5	22MAY2013	16:13	N	Double Read
					VISIT 6	21AUG2013	15:55	N	Double Read
					VISIT 7	19FEB2014	16:12	N	Double Read
					VISIT 8	18FEB2015	15:43	N	Double Read
					VISIT 11	14FEB2018	16:29	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	27NOV2012	19:55	N	Double Read
					VISIT 3A	18FEB2013	16:11	N	Double Read
					VISIT 3K	25FEB2013	16:21	N	Single Read
					VISIT 3L	12MAR2013	16:29	N	Single Read
					VISIT 4	03APR2013	15:56	N	Double Read
					VISIT 5	22MAY2013	16:13	N	Double Read
					VISIT 6	21AUG2013	15:55	N	Double Read
					VISIT 7	19FEB2014	16:12	N	Double Read
					VISIT 8	18FEB2015	15:43	N	Double Read
					VISIT 11	14FEB2018	16:29	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27NOV2012	19:55	N	Double Read
					VISIT 3A	18FEB2013	16:11	N	Double Read
					VISIT 3K	25FEB2013	16:21	N	Single Read
					VISIT 3L	12MAR2013	16:29	N	Single Read
					VISIT 4	03APR2013	15:56	N	Double Read
					VISIT 5	22MAY2013	16:13	N	Double Read
					VISIT 6	21AUG2013	15:55	N	Double Read
					VISIT 7	19FEB2014	16:12	N	Double Read
					VISIT 8	18FEB2015	15:43	N	Double Read
					VISIT 11	14FEB2018	16:29	N	Double Read
Normal lordotic LS	5_S		General		Baseline	27NOV2012	19:55	Y	Double Read
					VISIT 3A	18FEB2013	16:11	Y	Double Read
					VISIT 3K	25FEB2013	16:21	N	Single Read
					VISIT 3L	12MAR2013	16:29	N	Single Read
					VISIT 4	03APR2013	15:56	Y	Double Read
					VISIT 5	22MAY2013	16:13	Y	Double Read
					VISIT 6	21AUG2013	15:55	Y	Double Read
					VISIT 7	19FEB2014	16:12	Y	Double Read
					VISIT 8	18FEB2015	15:43	Y	Double Read
					VISIT 11	14FEB2018	16:29	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	27NOV2012	19:55	2	Double Read
					VISIT 3A	18FEB2013	16:11	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 3K	25FEB2013	16:21	0	Single Read
					VISIT 3L	12MAR2013	16:29	0	Single Read
					VISIT 4	03APR2013	15:56	2	Double Read
					VISIT 5	22MAY2013	16:13	0	Double Read
					VISIT 6	21AUG2013	15:55	0	Double Read
					VISIT 7	19FEB2014	16:12	2	Double Read
					VISIT 8	18FEB2015	15:43	1	Double Read
					VISIT 11	14FEB2018	16:29	1	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27NOV2012	19:55	0	Double Read
					VISIT 3A	18FEB2013	16:11	0	Double Read
					VISIT 3K	25FEB2013	16:21	0	Single Read
					VISIT 3L	12MAR2013	16:29	0	Single Read
					VISIT 4	03APR2013	15:56	0	Double Read
					VISIT 5	22MAY2013	16:13	0	Double Read
					VISIT 6	21AUG2013	15:55	0	Double Read
					VISIT 7	19FEB2014	16:12	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 8	18FEB2015	15:43	0	Double Read
					VISIT 11	14FEB2018	16:29	0	Double Read
					Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
					Baseline	27NOV2012	19:55	N	Double Read
					VISIT 3A	18FEB2013	16:11	N	Double Read
					VISIT 3K	25FEB2013	16:21	N	Single Read
					VISIT 3L	12MAR2013	16:29	N	Single Read
					VISIT 4	03APR2013	15:56	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 5	22MAY2013	16:13	N	Double Read
					VISIT 6	21AUG2013	15:55	N	Double Read
					VISIT 7	19FEB2014	16:12	N	Double Read
					VISIT 8	18FEB2015	15:43	N	Double Read
					VISIT 11	14FEB2018	16:29	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27NOV2012	19:55	N	Double Read
					VISIT 3A	18FEB2013	16:11	N	Double Read
					VISIT 3K	25FEB2013	16:21	N	Single Read
					VISIT 3L	12MAR2013	16:29	N	Single Read
					VISIT 4	03APR2013	15:56	N	Double Read
					VISIT 5	22MAY2013	16:13	N	Double Read
					VISIT 6	21AUG2013	15:55	N	Double Read
					VISIT 7	19FEB2014	16:12	N	Double Read
					VISIT 8	18FEB2015	15:43	N	Double Read
Relevant scoliosis	5_S		General		VISIT 11	14FEB2018	16:29	N	Double Read
					Baseline	27NOV2012	19:55	N	Double Read
					VISIT 3A	18FEB2013	16:11	N	Double Read
					VISIT 3K	25FEB2013	16:21	N	Single Read
					VISIT 3L	12MAR2013	16:29	N	Single Read
					VISIT 4	03APR2013	15:56	N	Double Read
					VISIT 5	22MAY2013	16:13	N	Double Read
					VISIT 6	21AUG2013	15:55	N	Double Read
					VISIT 7	19FEB2014	16:12	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		VISIT 8	18FEB2015	15:43	N	Double Read
					VISIT 11	14FEB2018	16:29	N	Double Read
					Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	27NOV2012	19:55	N	Double Read
					VISIT 3A	18FEB2013	16:11	N	Double Read
					VISIT 3K	25FEB2013	16:21	N	Single Read
					VISIT 3L	12MAR2013	16:29	N	Single Read
					VISIT 4	03APR2013	15:56	N	Double Read
					VISIT 5	22MAY2013	16:13	N	Double Read
					VISIT 6	21AUG2013	15:55	N	Double Read
					VISIT 7	19FEB2014	16:12	N	Double Read
					VISIT 8	18FEB2015	15:43	N	Double Read
					VISIT 11	14FEB2018	16:29	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27NOV2012	19:55	N	Double Read
					VISIT 3A	18FEB2013	16:11	N	Double Read
					VISIT 3K	25FEB2013	16:21	N	Single Read
					VISIT 3L	12MAR2013	16:29	N	Single Read
					VISIT 4	03APR2013	15:56	N	Double Read
					VISIT 5	22MAY2013	16:13	N	Double Read
					VISIT 6	21AUG2013	15:55	N	Double Read
					VISIT 7	19FEB2014	16:12	N	Double Read
					VISIT 8	18FEB2015	15:43	N	Double Read
					VISIT 11	14FEB2018	16:29	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 11	14FEB2018	16:29		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	27NOV2012	19:55	75.44304	Double Read
					VISIT 3A	18FEB2013	16:11	83.89488	Double Read
					VISIT 3K	25FEB2013	16:21	75.30528	Single Read
					VISIT 3L	12MAR2013	16:29	71.48224	Single Read
					VISIT 4	03APR2013	15:56	87.22384	Double Read
					VISIT 5	22MAY2013	16:13	81.83152	Double Read
					VISIT 6	21AUG2013	15:55	86.90096	Double Read
					VISIT 7	19FEB2014	16:12	65.98416	Double Read
					VISIT 8	18FEB2015	15:43	72.15312	Double Read
					VISIT 11	14FEB2018	16:29	70.36768	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21	81.36384	Single Read
					VISIT 3L	12MAR2013	16:29	87.53152	Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	27NOV2012	19:55	100.67616	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 3A	18FEB2013	16:11	102.8432	Double Read
					VISIT 3K	25FEB2013	16:21	99.17824	Single Read
					VISIT 3L	12MAR2013	16:29	100.13792	Single Read
					VISIT 4	03APR2013	15:56	105.332	Double Read
					VISIT 5	22MAY2013	16:13	103.05008	Double Read
					VISIT 6	21AUG2013	15:55	104.73472	Double Read
					VISIT 7	19FEB2014	16:12	92.34048	Double Read
					VISIT 8	18FEB2015	15:43	93.7216	Double Read
					VISIT 11	14FEB2018	16:29	92.08528	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21	107.52864	Single Read
					VISIT 3L	12MAR2013	16:29	106.04224	Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21	equal	Single Read
					VISIT 3L	12MAR2013	16:29	equal	Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21	equal	Single Read
					VISIT 3L	12MAR2013	16:29	equal	Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12	higher	Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	27NOV2012	19:55	lower	Double Read
					VISIT 3A	18FEB2013	16:11	lower	Double Read
					VISIT 3K	25FEB2013	16:21	lower	Single Read
					VISIT 3L	12MAR2013	16:29	lower	Single Read
					VISIT 4	03APR2013	15:56	lower	Double Read
					VISIT 5	22MAY2013	16:13	lower	Double Read
					VISIT 6	21AUG2013	15:55	lower	Double Read
					VISIT 7	19FEB2014	16:12	lower	Double Read
					VISIT 8	18FEB2015	15:43	lower	Double Read
					VISIT 11	14FEB2018	16:29	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12	equal	Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21	equal	Single Read
					VISIT 3L	12MAR2013	16:29	equal	Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21	equal	Single Read
					VISIT 3L	12MAR2013	16:29	equal	Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	27NOV2012	19:55	7.29901138101	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	18FEB2013	16:11	4.9485170715	Double Read
					VISIT 3K	25FEB2013	16:21	8.5763342959	Single Read
					VISIT 3L	12MAR2013	16:29	7.1343638525	Single Read
					VISIT 4	03APR2013	15:56	6.4943638525	Double Read
					VISIT 5	22MAY2013	16:13	6.7304637336	Double Read
					VISIT 6	21AUG2013	15:55	1.9413215559	Double Read
					VISIT 7	19FEB2014	16:12	9.2175165619	Double Read
					VISIT 8	18FEB2015	15:43	8.4822626125	Double Read
					VISIT 11	14FEB2018	16:29	9.1557669441	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21	8.7763954476	Single Read
					VISIT 3L	12MAR2013	16:29	8.2384915916	Single Read
					VISIT 4	03APR2013	15:56		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	27NOV2012	19:55	8.0176660438	Double Read
					VISIT 3A	18FEB2013	16:11	12.951866825	Double Read
					VISIT 3K	25FEB2013	16:21	11.324382537	Single Read
					VISIT 3L	12MAR2013	16:29	11.283207066	Single Read
					VISIT 4	03APR2013	15:56	8.1329709529	Double Read
					VISIT 5	22MAY2013	16:13	7.4316290130	Double Read
					VISIT 6	21AUG2013	15:55	7.7458807542	Double Read
					VISIT 7	19FEB2014	16:12	8.9103516222	Double Read
					VISIT 8	18FEB2015	15:43	10.039069135	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	14FEB2018	16:29	9.1701783591	Double Read
					Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21	2.7688126380	Single Read
					VISIT 3L	12MAR2013	16:29	11.720740614	Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	14FEB2018	16:29		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
Volume (mm ³) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	27NOV2012	19:55	18615.0	Double Read
					VISIT 3A	18FEB2013	16:11	18074.0	Double Read
					VISIT 3K	25FEB2013	16:21	18031	Single Read
					VISIT 3L	12MAR2013	16:29	18768	Single Read
					VISIT 4	03APR2013	15:56	18251.0	Double Read
					VISIT 5	22MAY2013	16:13	18115.5	Double Read
					VISIT 6	21AUG2013	15:55	17039.0	Double Read
					VISIT 7	19FEB2014	16:12	18032.0	Double Read
					VISIT 8	18FEB2015	15:43	18057.5	Double Read
					VISIT 11	14FEB2018	16:29	14017.0	Double Read
Volume (mm ³) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21		Single Read
					VISIT 3L	12MAR2013	16:29		Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
Volume (mm ³) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	27NOV2012	19:55		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0106 Age=48 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21	15471	Single Read
					VISIT 3L	12MAR2013	16:29	16145	Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	27NOV2012	19:55	26075.0	Double Read
					VISIT 3A	18FEB2013	16:11	26550.0	Double Read
					VISIT 3K	25FEB2013	16:21	25595	Single Read
					VISIT 3L	12MAR2013	16:29	25239	Single Read
					VISIT 4	03APR2013	15:56	25745.5	Double Read
					VISIT 5	22MAY2013	16:13	25087.0	Double Read
					VISIT 6	21AUG2013	15:55	25076.0	Double Read
					VISIT 7	19FEB2014	16:12	24368.0	Double Read
					VISIT 8	18FEB2015	15:43	26921.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	27NOV2012	19:55		Double Read
					VISIT 3A	18FEB2013	16:11		Double Read
					VISIT 3K	25FEB2013	16:21	10124	Single Read
					VISIT 3L	12MAR2013	16:29	9094	Single Read
					VISIT 4	03APR2013	15:56		Double Read
					VISIT 5	22MAY2013	16:13		Double Read
					VISIT 6	21AUG2013	15:55		Double Read
					VISIT 7	19FEB2014	16:12		Double Read
					VISIT 8	18FEB2015	15:43		Double Read
					VISIT 11	14FEB2018	16:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	08JAN2013	16:31	4	Double Read
					VISIT 3A	08APR2013	16:00	4	Double Read
					VISIT 3K	11APR2013	16:22	4	Single Read
					VISIT 3L	29APR2013	16:28	4	Single Read
					VISIT 4	15MAY2013	16:05	4	Double Read
					VISIT 5	03JUL2013	15:42	4	Double Read
					VISIT 6	25SEP2013	15:35	4	Double Read
					VISIT 7	28MAR2014	16:07	4	Double Read
					VISIT 8	08APR2015	15:59	4	Double Read
					VISIT 11	11APR2018	16:02	4	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	08JAN2013	16:31	2	Double Read
					VISIT 3A	08APR2013	16:00	2	Double Read
					VISIT 3K	11APR2013	16:22	3	Single Read
					VISIT 3L	29APR2013	16:28	3	Single Read
					VISIT 4	15MAY2013	16:05	2	Double Read
					VISIT 5	03JUL2013	15:42	2	Double Read
					VISIT 6	25SEP2013	15:35	2	Double Read
					VISIT 7	28MAR2014	16:07	2	Double Read
					VISIT 8	08APR2015	15:59	2	Double Read
					VISIT 11	11APR2018	16:02	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	08JAN2013	16:31	3	Double Read
					VISIT 3A	08APR2013	16:00	3	Double Read
					VISIT 3K	11APR2013	16:22	4	Single Read
					VISIT 3L	29APR2013	16:28	4	Single Read
					VISIT 4	15MAY2013	16:05	3	Double Read
					VISIT 5	03JUL2013	15:42	3	Double Read
					VISIT 6	25SEP2013	15:35	3	Double Read
					VISIT 7	28MAR2014	16:07	3	Double Read
					VISIT 8	08APR2015	15:59	4	Double Read
					VISIT 11	11APR2018	16:02	4	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	08JAN2013	16:31	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
					VISIT 11	11APR2018	16:02	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
					VISIT 11	11APR2018	16:02	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
					VISIT 11	11APR2018	16:02	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
					VISIT 11	11APR2018	16:02	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	4_5		General		VISIT 7	28MAR2014	16:07	N	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
					VISIT 11	11APR2018	16:02	N	Double Read
Fracture	4_5		General		Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
					VISIT 11	11APR2018	16:02	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	08JAN2013	16:31	14.35	Double Read
					VISIT 3A	08APR2013	16:00	13.685	Double Read
					VISIT 3K	11APR2013	16:22	13.23	Single Read
					VISIT 3L	29APR2013	16:28	13.41	Single Read
					VISIT 4	15MAY2013	16:05	12.21	Double Read
					VISIT 5	03JUL2013	15:42	12.08	Double Read
					VISIT 6	25SEP2013	15:35	13.215	Double Read
					VISIT 7	28MAR2014	16:07	12.595	Double Read
					VISIT 8	08APR2015	15:59	13.665	Double Read
					VISIT 11	11APR2018	16:02	9.16	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	08JAN2013	16:31	15.92	Double Read
					VISIT 3A	08APR2013	16:00	15.3	Double Read
					VISIT 3K	11APR2013	16:22	15.23	Single Read
					VISIT 3L	29APR2013	16:28	14.67	Single Read
					VISIT 4	15MAY2013	16:05	14.545	Double Read
					VISIT 5	03JUL2013	15:42	14.925	Double Read
					VISIT 6	25SEP2013	15:35	14.125	Double Read
					VISIT 7	28MAR2014	16:07	14.765	Double Read
					VISIT 8	08APR2015	15:59	15.555	Double Read
					VISIT 11	11APR2018	16:02	11.14	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	08JAN2013	16:31	13.58	Double Read
					VISIT 3A	08APR2013	16:00	12.85	Double Read
					VISIT 3K	11APR2013	16:22	12.68	Single Read
					VISIT 3L	29APR2013	16:28	12.50	Single Read
					VISIT 4	15MAY2013	16:05	12.765	Double Read
					VISIT 5	03JUL2013	15:42	12.645	Double Read
					VISIT 6	25SEP2013	15:35	13.495	Double Read
					VISIT 7	28MAR2014	16:07	12.67	Double Read
					VISIT 8	08APR2015	15:59	12.545	Double Read
					VISIT 11	11APR2018	16:02	11.145	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	08JAN2013	16:31	5.30216	Double Read
					VISIT 3A	08APR2013	16:00	5.932455	Double Read
					VISIT 3K	11APR2013	16:22	5.69789	Single Read
					VISIT 3L	29APR2013	16:28	5.44245	Single Read
					VISIT 4	15MAY2013	16:05	5.107815	Double Read
					VISIT 5	03JUL2013	15:42	5.12466	Double Read
					VISIT 6	25SEP2013	15:35	5.206955	Double Read
					VISIT 7	28MAR2014	16:07	4.56794	Double Read
					VISIT 8	08APR2015	15:59	5.341305	Double Read
					VISIT 11	11APR2018	16:02	4.575605	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	08JAN2013	16:31	13.31185	Double Read
					VISIT 3A	08APR2013	16:00	11.898	Double Read
					VISIT 3K	11APR2013	16:22	12.3622	Single Read
					VISIT 3L	29APR2013	16:28	12.5187	Single Read
					VISIT 4	15MAY2013	16:05	11.3329	Double Read
					VISIT 5	03JUL2013	15:42	11.15135	Double Read
					VISIT 6	25SEP2013	15:35	11.1976	Double Read
					VISIT 7	28MAR2014	16:07	11.5725	Double Read
					VISIT 8	08APR2015	15:59	10.64625	Double Read
					VISIT 11	11APR2018	16:02	9.37055	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	08JAN2013	16:31	10.086655	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	VISIT 3A	08APR2013	16:00	9.07101	Double Read
					VISIT 3K	11APR2013	16:22	9.60309	Single Read
					VISIT 3L	29APR2013	16:28	9.27298	Single Read
					VISIT 4	15MAY2013	16:05	8.84123	Double Read
					VISIT 5	03JUL2013	15:42	9.119335	Double Read
					VISIT 6	25SEP2013	15:35	9.186725	Double Read
					VISIT 7	28MAR2014	16:07	8.527275	Double Read
					VISIT 8	08APR2015	15:59	7.91847	Double Read
					VISIT 11	11APR2018	16:02	8.05858	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
					VISIT 11	11APR2018	16:02	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
					VISIT 11	11APR2018	16:02	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
					VISIT 11	11APR2018	16:02	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
					VISIT 11	11APR2018	16:02	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
					VISIT 11	11APR2018	16:02	N	Double Read
Normal lordotic LS	4_5		General		Baseline	08JAN2013	16:31	Y	Double Read
					VISIT 3A	08APR2013	16:00	Y	Double Read
					VISIT 3K	11APR2013	16:22	Y	Single Read
					VISIT 3L	29APR2013	16:28	Y	Single Read
					VISIT 4	15MAY2013	16:05	Y	Double Read
					VISIT 5	03JUL2013	15:42	Y	Double Read
					VISIT 6	25SEP2013	15:35	Y	Double Read
					VISIT 7	28MAR2014	16:07	Y	Double Read
					VISIT 8	08APR2015	15:59	Y	Double Read
					VISIT 11	11APR2018	16:02	N	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	08JAN2013	16:31	2	Double Read
					VISIT 3A	08APR2013	16:00	2	Double Read
					VISIT 3K	11APR2013	16:22	2	Single Read
					VISIT 3L	29APR2013	16:28	2	Single Read
					VISIT 4	15MAY2013	16:05	2	Double Read
					VISIT 5	03JUL2013	15:42	2	Double Read
					VISIT 6	25SEP2013	15:35	2	Double Read
					VISIT 7	28MAR2014	16:07	2	Double Read
					VISIT 8	08APR2015	15:59	2	Double Read
					VISIT 11	11APR2018	16:02	2	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	08JAN2013	16:31	0	Double Read
					VISIT 3A	08APR2013	16:00	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 3K	11APR2013	16:22	0	Single Read
					VISIT 3L	29APR2013	16:28	0	Single Read
					VISIT 4	15MAY2013	16:05	0	Double Read
					VISIT 5	03JUL2013	15:42	0	Double Read
					VISIT 6	25SEP2013	15:35	0	Double Read
					VISIT 7	28MAR2014	16:07	0	Double Read
					VISIT 8	08APR2015	15:59	0	Double Read
					VISIT 11	11APR2018	16:02	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	08JAN2013	16:31	0	Double Read
					VISIT 3A	08APR2013	16:00	0	Double Read
					VISIT 3K	11APR2013	16:22	0	Single Read
					VISIT 3L	29APR2013	16:28	0	Single Read
					VISIT 4	15MAY2013	16:05	0	Double Read
					VISIT 5	03JUL2013	15:42	0	Double Read
					VISIT 6	25SEP2013	15:35	0	Double Read
					VISIT 7	28MAR2014	16:07	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 8	08APR2015	15:59	0	Double Read
					VISIT 11	11APR2018	16:02	0	Double Read
					Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	Y	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
					VISIT 11	11APR2018	16:02	N	Double Read
					Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
					VISIT 11	11APR2018	16:02	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
Relevant scoliosis	4_5		General		VISIT 11	11APR2018	16:02	N	Double Read
					Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		VISIT 8	08APR2015	15:59	N	Double Read
					VISIT 11	11APR2018	16:02	N	Double Read
					Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		VISIT 8	08APR2015	15:59	N	Double Read
					VISIT 11	11APR2018	16:02	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
					VISIT 11	11APR2018	16:02	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	08JAN2013	16:31	N	Double Read
					VISIT 3A	08APR2013	16:00	N	Double Read
					VISIT 3K	11APR2013	16:22	N	Single Read
					VISIT 3L	29APR2013	16:28	N	Single Read
					VISIT 4	15MAY2013	16:05	N	Double Read
					VISIT 5	03JUL2013	15:42	N	Double Read
					VISIT 6	25SEP2013	15:35	N	Double Read
					VISIT 7	28MAR2014	16:07	N	Double Read
					VISIT 8	08APR2015	15:59	N	Double Read
					VISIT 11	11APR2018	16:02	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22		Single Read
					VISIT 3L	29APR2013	16:28		Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 11	11APR2018	16:02		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	08JAN2013	16:31	88.84528	Double Read
					VISIT 3A	08APR2013	16:00	92.47088	Double Read
					VISIT 3K	11APR2013	16:22	88.46592	Single Read
					VISIT 3L	29APR2013	16:28	104.50368	Single Read
					VISIT 4	15MAY2013	16:05	92.92896	Double Read
					VISIT 5	03JUL2013	15:42	88.55824	Double Read
					VISIT 6	25SEP2013	15:35	95.11792	Double Read
					VISIT 7	28MAR2014	16:07	74.19936	Double Read
					VISIT 8	08APR2015	15:59	76.90112	Double Read
					VISIT 11	11APR2018	16:02	73.06928	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22		Single Read
					VISIT 3L	29APR2013	16:28		Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22	90.17856	Single Read
					VISIT 3L	29APR2013	16:28	107.1808	Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	08JAN2013	16:31	88.7408	Double Read
					VISIT 3A	08APR2013	16:00	87.9288	Double Read
					VISIT 3K	11APR2013	16:22	94.2464	Single Read
					VISIT 3L	29APR2013	16:28	93.2992	Single Read
					VISIT 4	15MAY2013	16:05	90.52448	Double Read
					VISIT 5	03JUL2013	15:42	89.52032	Double Read
					VISIT 6	25SEP2013	15:35	89.98848	Double Read
					VISIT 7	28MAR2014	16:07	80.26304	Double Read
					VISIT 8	08APR2015	15:59	81.68928	Double Read
					VISIT 11	11APR2018	16:02	70.0968	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22	95.63776	Single Read
					VISIT 3L	29APR2013	16:28	93.93024	Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22		Single Read
					VISIT 3L	29APR2013	16:28		Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	08JAN2013	16:31	78.46768	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	VISIT 3A	08APR2013	16:00	77.85856	Double Read
					VISIT 3K	11APR2013	16:22	86.00448	Single Read
					VISIT 3L	29APR2013	16:28	81.13984	Single Read
					VISIT 4	15MAY2013	16:05	83.94608	Double Read
					VISIT 5	03JUL2013	15:42	80.36768	Double Read
					VISIT 6	25SEP2013	15:35	86.07424	Double Read
					VISIT 7	28MAR2014	16:07	68.30288	Double Read
					VISIT 8	08APR2015	15:59	71.14736	Double Read
					VISIT 11	11APR2018	16:02	69.25504	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22		Single Read
					VISIT 3L	29APR2013	16:28		Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22	equal	Single Read
					VISIT 3L	29APR2013	16:28	equal	Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22	equal	Single Read
					VISIT 3L	29APR2013	16:28	equal	Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22	equal	Single Read
					VISIT 3L	29APR2013	16:28	equal	Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22		Single Read
					VISIT 3L	29APR2013	16:28		Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	08JAN2013	16:31	higher	Double Read
					VISIT 3A	08APR2013	16:00	higher	Double Read
					VISIT 3K	11APR2013	16:22	higher	Single Read
					VISIT 3L	29APR2013	16:28	higher	Single Read
					VISIT 4	15MAY2013	16:05	higher	Double Read
					VISIT 5	03JUL2013	15:42	higher	Double Read
					VISIT 6	25SEP2013	15:35	higher	Double Read
					VISIT 7	28MAR2014	16:07	higher	Double Read
					VISIT 8	08APR2015	15:59	higher	Double Read
					VISIT 11	11APR2018	16:02	higher	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22		Single Read
					VISIT 3L	29APR2013	16:28		Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22		Single Read
					VISIT 3L	29APR2013	16:28		Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	08JAN2013	16:31	higher	Double Read
					VISIT 3A	08APR2013	16:00	higher	Double Read
					VISIT 3K	11APR2013	16:22	higher	Single Read
					VISIT 3L	29APR2013	16:28	higher	Single Read
					VISIT 4	15MAY2013	16:05	higher	Double Read
					VISIT 5	03JUL2013	15:42	higher	Double Read
					VISIT 6	25SEP2013	15:35	higher	Double Read
					VISIT 7	28MAR2014	16:07	higher	Double Read
					VISIT 8	08APR2015	15:59	higher	Double Read
					VISIT 11	11APR2018	16:02	higher	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22		Single Read
					VISIT 3L	29APR2013	16:28		Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22	equal	Single Read
					VISIT 3L	29APR2013	16:28	equal	Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22	equal	Single Read
					VISIT 3L	29APR2013	16:28	equal	Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22	equal	Single Read
					VISIT 3L	29APR2013	16:28	equal	Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22		Single Read
					VISIT 3L	29APR2013	16:28		Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	08JAN2013	16:31	6.90787837608	Double Read
					VISIT 3A	08APR2013	16:00	8.28945133345	Double Read
					VISIT 3K	11APR2013	16:22	2.62078478002	Single Read
					VISIT 3L	29APR2013	16:28	5.20921352132	Single Read
					VISIT 4	15MAY2013	16:05	3.60664515033	Double Read
					VISIT 5	03JUL2013	15:42	4.15914387634	Double Read
					VISIT 6	25SEP2013	15:35	3.36247324613	Double Read
					VISIT 7	28MAR2014	16:07	8.90581960251	Double Read
					VISIT 8	08APR2015	15:59	5.42357057924	Double Read
					VISIT 11	11APR2018	16:02	7.10888398166	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22		Single Read
					VISIT 3L	29APR2013	16:28		Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22	2.88771870223	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	VISIT 3L	29APR2013	16:28	36.3102429081	Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	08JAN2013	16:31	8.87529811447	Double Read
					VISIT 3A	08APR2013	16:00	19.0444029217	Double Read
					VISIT 3K	11APR2013	16:22	3.27377611687	Single Read
					VISIT 3L	29APR2013	16:28	4.41651095634	Single Read
					VISIT 4	15MAY2013	16:05	12.5127093596	Double Read
					VISIT 5	03JUL2013	15:42	10.7552641414	Double Read
					VISIT 6	25SEP2013	15:35	11.0747885174	Double Read
					VISIT 7	28MAR2014	16:07	9.6597044335	Double Read
					VISIT 8	08APR2015	15:59	5.83475454391	Double Read
					VISIT 11	11APR2018	16:02	7.70929165959	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22	3.12708000679	Single Read
					VISIT 3L	29APR2013	16:28	4.28061831153	Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22		Single Read
					VISIT 3L	29APR2013	16:28		Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	08JAN2013	16:31	9.75029726516	Double Read
					VISIT 3A	08APR2013	16:00	8.9859011381	Double Read
					VISIT 3K	11APR2013	16:22	9.46394428402	Single Read
					VISIT 3L	29APR2013	16:28	7.13436385256	Single Read
					VISIT 4	15MAY2013	16:05	8.73368438934	Double Read
					VISIT 5	03JUL2013	15:42	8.54182435876	Double Read
					VISIT 6	25SEP2013	15:35	6.70403940887	Double Read
					VISIT 7	28MAR2014	16:07	9.33600135894	Double Read
					VISIT 8	08APR2015	15:59	6.79463224053	Double Read
					VISIT 11	11APR2018	16:02	6.13026668932	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22		Single Read
					VISIT 3L	29APR2013	16:28		Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22		Single Read
					VISIT 3L	29APR2013	16:28		Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	08JAN2013	16:31	10284.0	Double Read
					VISIT 3A	08APR2013	16:00	11351.0	Double Read
					VISIT 3K	11APR2013	16:22	10435	Single Read
					VISIT 3L	29APR2013	16:28	10335	Single Read
					VISIT 4	15MAY2013	16:05	9368.0	Double Read
					VISIT 5	03JUL2013	15:42	8967.0	Double Read
					VISIT 6	25SEP2013	15:35	10696.0	Double Read
					VISIT 7	28MAR2014	16:07	10280.5	Double Read
					VISIT 8	08APR2015	15:59	11609.5	Double Read
					VISIT 11	11APR2018	16:02	7518.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	08JAN2013	16:31		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22		Single Read
					VISIT 3L	29APR2013	16:28		Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read
Volume (mm ³) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22	11379	Single Read
					VISIT 3L	29APR2013	16:28	9561	Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read
Volume (mm ³) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	08JAN2013	16:31	18227.0	Double Read
					VISIT 3A	08APR2013	16:00	17958.0	Double Read
					VISIT 3K	11APR2013	16:22	19231	Single Read
					VISIT 3L	29APR2013	16:28	18854	Single Read
					VISIT 4	15MAY2013	16:05	17233.5	Double Read
					VISIT 5	03JUL2013	15:42	18582.5	Double Read
					VISIT 6	25SEP2013	15:35	17140.5	Double Read
					VISIT 7	28MAR2014	16:07	16783.5	Double Read
					VISIT 8	08APR2015	15:59	18143.5	Double Read
					VISIT 11	11APR2018	16:02	14742.0	Double Read
Volume (mm ³) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 3K	11APR2013	16:22	7852	Single Read
					VISIT 3L	29APR2013	16:28	9293	Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read
Volume (mm ³) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22		Single Read
					VISIT 3L	29APR2013	16:28		Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
Volume (mm ³) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	08JAN2013	16:31	15490.0	Double Read
					VISIT 3A	08APR2013	16:00	15239.5	Double Read
					VISIT 3K	11APR2013	16:22	15474	Single Read
					VISIT 3L	29APR2013	16:28	16755	Single Read
					VISIT 4	15MAY2013	16:05	14663.0	Double Read
					VISIT 5	03JUL2013	15:42	14545.0	Double Read
					VISIT 6	25SEP2013	15:35	14879.5	Double Read
					VISIT 7	28MAR2014	16:07	14924.0	Double Read
Volume (mm ³) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	08APR2015	15:59	15126.0	Double Read
					VISIT 11	11APR2018	16:02	12954.5	Double Read
					Baseline	08JAN2013	16:31		Double Read
					VISIT 3A	08APR2013	16:00		Double Read
					VISIT 3K	11APR2013	16:22		Single Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0107 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 3L	29APR2013	16:28		Single Read
					VISIT 4	15MAY2013	16:05		Double Read
					VISIT 5	03JUL2013	15:42		Double Read
					VISIT 6	25SEP2013	15:35		Double Read
					VISIT 7	28MAR2014	16:07		Double Read
					VISIT 8	08APR2015	15:59		Double Read
					VISIT 11	11APR2018	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	09JAN2013	15:54	3	Double Read
					VISIT 3A	15APR2013	16:18	4	Double Read
					VISIT 3K	18APR2013	16:30	4	Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52	4	Double Read
					VISIT 5	11JUL2013	16:01	4	Double Read
					VISIT 6	01OCT2013	16:42	4	Double Read
					VISIT 7	02APR2014	16:01	4	Double Read
					VISIT 8	16APR2015	16:00	4	Double Read
					VISIT 11	21MAR2018	16:16	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	09JAN2013	15:54	3	Double Read
					VISIT 3A	15APR2013	16:18	3	Double Read
					VISIT 3K	18APR2013	16:30	3	Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52	3	Double Read
					VISIT 5	11JUL2013	16:01	3	Double Read
					VISIT 6	01OCT2013	16:42	3	Double Read
					VISIT 7	02APR2014	16:01	3	Double Read
					VISIT 8	16APR2015	16:00	3	Double Read
					VISIT 11	21MAR2018	16:16	4	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	09JAN2013	15:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	09JAN2013	15:54	N	Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30	N	Single Read
					VISIT 3L	08MAY2013	16:36	N	Single Read
					VISIT 4	29MAY2013	15:52	N	Double Read
					VISIT 5	11JUL2013	16:01	N	Double Read
					VISIT 6	01OCT2013	16:42	N	Double Read
					VISIT 7	02APR2014	16:01	N	Double Read
					VISIT 8	16APR2015	16:00	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	09JAN2013	15:54	N	Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30	N	Single Read
					VISIT 3L	08MAY2013	16:36	N	Single Read
					VISIT 4	29MAY2013	15:52	N	Double Read
					VISIT 5	11JUL2013	16:01	N	Double Read
					VISIT 6	01OCT2013	16:42	N	Double Read
					VISIT 7	02APR2014	16:01	N	Double Read
					VISIT 8	16APR2015	16:00	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	09JAN2013	15:54	Y	Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30	Y	Single Read
					VISIT 3L	08MAY2013	16:36	Y	Single Read
					VISIT 4	29MAY2013	15:52	Y	Double Read
					VISIT 5	11JUL2013	16:01	Y	Double Read
					VISIT 6	01OCT2013	16:42	N	Double Read
					VISIT 7	02APR2014	16:01	N	Double Read
					VISIT 8	16APR2015	16:00	N	Double Read
					VISIT 11	21MAR2018	16:16	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	09JAN2013	15:54	N	Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30	N	Single Read
					VISIT 3L	08MAY2013	16:36	N	Single Read
					VISIT 4	29MAY2013	15:52	N	Double Read
					VISIT 5	11JUL2013	16:01	N	Double Read
					VISIT 6	01OCT2013	16:42	N	Double Read
					VISIT 7	02APR2014	16:01	N	Double Read
					VISIT 8	16APR2015	16:00	N	Double Read
					VISIT 11	21MAR2018	16:16	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	09JAN2013	15:54	N	Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30	N	Single Read
					VISIT 3L	08MAY2013	16:36	N	Single Read
					VISIT 4	29MAY2013	15:52	N	Double Read
					VISIT 5	11JUL2013	16:01	N	Double Read
					VISIT 6	01OCT2013	16:42	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 7	02APR2014	16:01	N	Double Read
					VISIT 8	16APR2015	16:00	N	Double Read
					VISIT 11	21MAR2018	16:16	N	Double Read
Fracture	5_S		General		Baseline	09JAN2013	15:54	N	Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30	N	Single Read
					VISIT 3L	08MAY2013	16:36	N	Single Read
					VISIT 4	29MAY2013	15:52	N	Double Read
					VISIT 5	11JUL2013	16:01	N	Double Read
					VISIT 6	01OCT2013	16:42	N	Double Read
					VISIT 7	02APR2014	16:01	N	Double Read
					VISIT 8	16APR2015	16:00	N	Double Read
					VISIT 11	21MAR2018	16:16	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	09JAN2013	15:54	13.97	Double Read
					VISIT 3A	15APR2013	16:18	14.625	Double Read
					VISIT 3K	18APR2013	16:30	16.09	Single Read
					VISIT 3L	08MAY2013	16:36	12.90	Single Read
					VISIT 4	29MAY2013	15:52	13.015	Double Read
					VISIT 5	11JUL2013	16:01	14.165	Double Read
					VISIT 6	01OCT2013	16:42	13.39	Double Read
					VISIT 7	02APR2014	16:01	14.565	Double Read
					VISIT 8	16APR2015	16:00	13.475	Double Read
					VISIT 11	21MAR2018	16:16	12.405	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	09JAN2013	15:54	15.955	Double Read
					VISIT 3A	15APR2013	16:18	18.36	Double Read
					VISIT 3K	18APR2013	16:30	14.83	Single Read
					VISIT 3L	08MAY2013	16:36	13.33	Single Read
					VISIT 4	29MAY2013	15:52	17.02	Double Read
					VISIT 5	11JUL2013	16:01	16.3	Double Read
					VISIT 6	01OCT2013	16:42	16.54	Double Read
					VISIT 7	02APR2014	16:01	16.28	Double Read
					VISIT 8	16APR2015	16:00	16.385	Double Read
					VISIT 11	21MAR2018	16:16	14.815	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	09JAN2013	15:54	8.27857	Double Read
					VISIT 3A	15APR2013	16:18	8.847575	Double Read
					VISIT 3K	18APR2013	16:30	9.89405	Single Read
					VISIT 3L	08MAY2013	16:36	8.73155	Single Read
					VISIT 4	29MAY2013	15:52	8.691035	Double Read
					VISIT 5	11JUL2013	16:01	9.333	Double Read
					VISIT 6	01OCT2013	16:42	8.686505	Double Read
					VISIT 7	02APR2014	16:01	9.711335	Double Read
					VISIT 8	16APR2015	16:00	7.4034	Double Read
					VISIT 11	21MAR2018	16:16	8.42383	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	09JAN2013	15:54	10.20506	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 3A	15APR2013	16:18	10.57705	Double Read
					VISIT 3K	18APR2013	16:30	11.6919	Single Read
					VISIT 3L	08MAY2013	16:36	10.2377	Single Read
					VISIT 4	29MAY2013	15:52	10.246595	Double Read
					VISIT 5	11JUL2013	16:01	11.4676	Double Read
					VISIT 6	01OCT2013	16:42	12.05985	Double Read
					VISIT 7	02APR2014	16:01	11.49185	Double Read
					VISIT 8	16APR2015	16:00	11.5304	Double Read
					VISIT 11	21MAR2018	16:16	11.85835	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	09JAN2013	15:54	N	Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30	N	Single Read
					VISIT 3L	08MAY2013	16:36	N	Single Read
					VISIT 4	29MAY2013	15:52	N	Double Read
					VISIT 5	11JUL2013	16:01	N	Double Read
					VISIT 6	01OCT2013	16:42	N	Double Read
					VISIT 7	02APR2014	16:01	N	Double Read
					VISIT 8	16APR2015	16:00	N	Double Read
					VISIT 11	21MAR2018	16:16	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	09JAN2013	15:54	N	Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30	N	Single Read
					VISIT 3L	08MAY2013	16:36	N	Single Read
					VISIT 4	29MAY2013	15:52	N	Double Read
					VISIT 5	11JUL2013	16:01	N	Double Read
					VISIT 6	01OCT2013	16:42	N	Double Read
					VISIT 7	02APR2014	16:01	N	Double Read
					VISIT 8	16APR2015	16:00	N	Double Read
					VISIT 11	21MAR2018	16:16	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	09JAN2013	15:54	N	Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30	N	Single Read
					VISIT 3L	08MAY2013	16:36	N	Single Read
					VISIT 4	29MAY2013	15:52	N	Double Read
					VISIT 5	11JUL2013	16:01	N	Double Read
					VISIT 6	01OCT2013	16:42	N	Double Read
					VISIT 7	02APR2014	16:01	N	Double Read
					VISIT 8	16APR2015	16:00	N	Double Read
					VISIT 11	21MAR2018	16:16	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	09JAN2013	15:54	N	Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30	N	Single Read
					VISIT 3L	08MAY2013	16:36	N	Single Read
					VISIT 4	29MAY2013	15:52	N	Double Read
					VISIT 5	11JUL2013	16:01	N	Double Read
					VISIT 6	01OCT2013	16:42	N	Double Read
					VISIT 7	02APR2014	16:01	N	Double Read
					VISIT 8	16APR2015	16:00	N	Double Read
					VISIT 11	21MAR2018	16:16	N	Double Read
Normal lordotic LS	5_S		General		Baseline	09JAN2013	15:54	Y	Double Read
					VISIT 3A	15APR2013	16:18	Y	Double Read
					VISIT 3K	18APR2013	16:30	Y	Single Read
					VISIT 3L	08MAY2013	16:36	Y	Single Read
					VISIT 4	29MAY2013	15:52	Y	Double Read
					VISIT 5	11JUL2013	16:01	Y	Double Read
					VISIT 6	01OCT2013	16:42	Y	Double Read
					VISIT 7	02APR2014	16:01	Y	Double Read
					VISIT 8	16APR2015	16:00	Y	Double Read
					VISIT 11	21MAR2018	16:16	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18	0	Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	09JAN2013	15:54	0	Double Read
					VISIT 3A	15APR2013	16:18	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 3K	18APR2013	16:30	0	Single Read
					VISIT 3L	08MAY2013	16:36	0	Single Read
					VISIT 4	29MAY2013	15:52	0	Double Read
					VISIT 5	11JUL2013	16:01	0	Double Read
					VISIT 6	01OCT2013	16:42	0	Double Read
					VISIT 7	02APR2014	16:01	0	Double Read
					VISIT 8	16APR2015	16:00	0	Double Read
					VISIT 11	21MAR2018	16:16	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	09JAN2013	15:54	0	Double Read
					VISIT 3A	15APR2013	16:18	0	Double Read
					VISIT 3K	18APR2013	16:30	0	Single Read
					VISIT 3L	08MAY2013	16:36	0	Single Read
					VISIT 4	29MAY2013	15:52	0	Double Read
					VISIT 5	11JUL2013	16:01	0	Double Read
					VISIT 6	01OCT2013	16:42	0	Double Read
					VISIT 7	02APR2014	16:01	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 8	16APR2015	16:00	0	Double Read
					VISIT 11	21MAR2018	16:16	0	Double Read
					Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
					Baseline	09JAN2013	15:54	N	Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30	N	Single Read
					VISIT 3L	08MAY2013	16:36	N	Single Read
					VISIT 4	29MAY2013	15:52	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 5	11JUL2013	16:01	N	Double Read
					VISIT 6	01OCT2013	16:42	N	Double Read
					VISIT 7	02APR2014	16:01	N	Double Read
					VISIT 8	16APR2015	16:00	N	Double Read
					VISIT 11	21MAR2018	16:16	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	09JAN2013	15:54	N	Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30	N	Single Read
					VISIT 3L	08MAY2013	16:36	N	Single Read
					VISIT 4	29MAY2013	15:52	N	Double Read
					VISIT 5	11JUL2013	16:01	N	Double Read
					VISIT 6	01OCT2013	16:42	N	Double Read
					VISIT 7	02APR2014	16:01	N	Double Read
					VISIT 8	16APR2015	16:00	N	Double Read
Relevant scoliosis	5_S		General		VISIT 11	21MAR2018	16:16	N	Double Read
					Baseline	09JAN2013	15:54	N	Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30	Y	Single Read
					VISIT 3L	08MAY2013	16:36	N	Single Read
					VISIT 4	29MAY2013	15:52	N	Double Read
					VISIT 5	11JUL2013	16:01	N	Double Read
					VISIT 6	01OCT2013	16:42	N	Double Read
					VISIT 7	02APR2014	16:01	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		VISIT 8	16APR2015	16:00	N	Double Read
					VISIT 11	21MAR2018	16:16	N	Double Read
					Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	09JAN2013	15:54	N	Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30	N	Single Read
					VISIT 3L	08MAY2013	16:36	N	Single Read
					VISIT 4	29MAY2013	15:52	N	Double Read
					VISIT 5	11JUL2013	16:01	N	Double Read
					VISIT 6	01OCT2013	16:42	N	Double Read
					VISIT 7	02APR2014	16:01	N	Double Read
					VISIT 8	16APR2015	16:00	N	Double Read
					VISIT 11	21MAR2018	16:16	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	09JAN2013	15:54	N	Double Read
					VISIT 3A	15APR2013	16:18	N	Double Read
					VISIT 3K	18APR2013	16:30	N	Single Read
					VISIT 3L	08MAY2013	16:36	N	Single Read
					VISIT 4	29MAY2013	15:52	N	Double Read
					VISIT 5	11JUL2013	16:01	N	Double Read
					VISIT 6	01OCT2013	16:42	N	Double Read
					VISIT 7	02APR2014	16:01	N	Double Read
					VISIT 8	16APR2015	16:00	N	Double Read
					VISIT 11	21MAR2018	16:16	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 11	21MAR2018	16:16		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	09JAN2013	15:54	82.68016	Double Read
					VISIT 3A	15APR2013	16:18	84.0064	Double Read
					VISIT 3K	18APR2013	16:30	84.97504	Single Read
					VISIT 3L	08MAY2013	16:36	93.03968	Single Read
					VISIT 4	29MAY2013	15:52	81.36192	Double Read
					VISIT 5	11JUL2013	16:01	78.1288	Double Read
					VISIT 6	01OCT2013	16:42	93.75824	Double Read
					VISIT 7	02APR2014	16:01	72.00752	Double Read
					VISIT 8	16APR2015	16:00	77.592	Double Read
					VISIT 11	21MAR2018	16:16	69.10368	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30	110.1104	Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	09JAN2013	15:54	85.82336	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 3A	15APR2013	16:18	82.48624	Double Read
					VISIT 3K	18APR2013	16:30	87.47648	Single Read
					VISIT 3L	08MAY2013	16:36	83.92768	Single Read
					VISIT 4	29MAY2013	15:52	80.48896	Double Read
					VISIT 5	11JUL2013	16:01	77.36064	Double Read
					VISIT 6	01OCT2013	16:42	82.14288	Double Read
					VISIT 7	02APR2014	16:01	66.96672	Double Read
					VISIT 8	16APR2015	16:00	76.6032	Double Read
					VISIT 11	21MAR2018	16:16	71.66576	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18	81.48352	Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30	equal	Single Read
					VISIT 3L	08MAY2013	16:36	equal	Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30	equal	Single Read
					VISIT 3L	08MAY2013	16:36	equal	Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01	equal	Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	09JAN2013	15:54	equal	Double Read
					VISIT 3A	15APR2013	16:18	lower	Double Read
					VISIT 3K	18APR2013	16:30	lower	Single Read
					VISIT 3L	08MAY2013	16:36	lower	Single Read
					VISIT 4	29MAY2013	15:52	lower	Double Read
					VISIT 5	11JUL2013	16:01	lower	Double Read
					VISIT 6	01OCT2013	16:42	lower	Double Read
					VISIT 7	02APR2014	16:01	equal	Double Read
					VISIT 8	16APR2015	16:00	equal	Double Read
					VISIT 11	21MAR2018	16:16	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01	lower	Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30	equal	Single Read
					VISIT 3L	08MAY2013	16:36	equal	Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30	equal	Single Read
					VISIT 3L	08MAY2013	16:36	equal	Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	09JAN2013	15:54	6.03448275862	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	15APR2013	16:18	6.78613895023	Double Read
					VISIT 3K	18APR2013	16:30	8.7197825717	Single Read
					VISIT 3L	08MAY2013	16:36	5.43570579242	Single Read
					VISIT 4	29MAY2013	15:52	3.91618141668	Double Read
					VISIT 5	11JUL2013	16:01	7.86640394089	Double Read
					VISIT 6	01OCT2013	16:42	7.1494615254	Double Read
					VISIT 7	02APR2014	16:01	7.0478613895	Double Read
					VISIT 8	16APR2015	16:00	6.37351452352	Double Read
					VISIT 11	21MAR2018	16:16	6.89655172414	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30	27.5304909122	Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	09JAN2013	15:54	6.1384881943	Double Read
					VISIT 3A	15APR2013	16:18	10.841753015	Double Read
					VISIT 3K	18APR2013	16:30	6.1751248513	Single Read
					VISIT 3L	08MAY2013	16:36	6.3190079836	Single Read
					VISIT 4	29MAY2013	15:52	8.4593171394	Double Read
					VISIT 5	11JUL2013	16:01	6.9715101070	Double Read
					VISIT 6	01OCT2013	16:42	6.2013725157	Double Read
					VISIT 7	02APR2014	16:01	8.3543400713	Double Read
					VISIT 8	16APR2015	16:00	11.301736028	Double Read
					VISIT 11	21MAR2018	16:16	8.0254187192	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30	6.2224562595	Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	09JAN2013	15:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
Volume (mm ³) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	09JAN2013	15:54	12981.5	Double Read
					VISIT 3A	15APR2013	16:18	13516.5	Double Read
					VISIT 3K	18APR2013	16:30	13216	Single Read
					VISIT 3L	08MAY2013	16:36	12249	Single Read
					VISIT 4	29MAY2013	15:52	11441.5	Double Read
					VISIT 5	11JUL2013	16:01	12613.0	Double Read
					VISIT 6	01OCT2013	16:42	13173.0	Double Read
					VISIT 7	02APR2014	16:01	12738.5	Double Read
					VISIT 8	16APR2015	16:00	12574.0	Double Read
Volume (mm ³) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30		Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
Volume (mm ³) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0108 Age=37 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	VISIT 3K	18APR2013	16:30	9753	Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read
Volume (mm ³) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	09JAN2013	15:54	19012.0	Double Read
					VISIT 3A	15APR2013	16:18	20517.5	Double Read
					VISIT 3K	18APR2013	16:30	18776	Single Read
					VISIT 3L	08MAY2013	16:36	18347	Single Read
					VISIT 4	29MAY2013	15:52	18462.5	Double Read
					VISIT 5	11JUL2013	16:01	19534.0	Double Read
					VISIT 6	01OCT2013	16:42	19714.5	Double Read
					VISIT 7	02APR2014	16:01	19158.0	Double Read
					VISIT 8	16APR2015	16:00	20205.5	Double Read
					VISIT 11	21MAR2018	16:16	17865.5	Double Read
Volume (mm ³) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	09JAN2013	15:54		Double Read
					VISIT 3A	15APR2013	16:18		Double Read
					VISIT 3K	18APR2013	16:30	9023	Single Read
					VISIT 3L	08MAY2013	16:36		Single Read
					VISIT 4	29MAY2013	15:52		Double Read
					VISIT 5	11JUL2013	16:01		Double Read
					VISIT 6	01OCT2013	16:42		Double Read
					VISIT 7	02APR2014	16:01		Double Read
					VISIT 8	16APR2015	16:00		Double Read
					VISIT 11	21MAR2018	16:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S	4_5	Central Disc		Baseline	22JAN2013	16:04	3	Double Read
					VISIT 3A	22APR2013	15:57	4	Double Read
					VISIT 3K	25APR2013	16:34	4	Single Read
					VISIT 3L	15MAY2013	17:20	4	Single Read
					VISIT 4	06JUN2013	15:52	3	Double Read
					VISIT 5	31JUL2013	15:52	3	Double Read
					VISIT 6	15OCT2013	16:00	4	Double Read
					VISIT 7	09APR2014	16:14	4	Double Read
					VISIT 8	22APR2015	16:43	3	Double Read
					VISIT 11	28MAR2018	16:24	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22JAN2013	16:04	3	Double Read
					VISIT 3A	22APR2013	15:57	4	Double Read
					VISIT 3K	25APR2013	16:34	4	Single Read
					VISIT 3L	15MAY2013	17:20	4	Single Read
					VISIT 4	06JUN2013	15:52	3	Double Read
					VISIT 5	31JUL2013	15:52	3	Double Read
					VISIT 6	15OCT2013	16:00	3	Double Read
					VISIT 7	09APR2014	16:14	4	Double Read
					VISIT 8	22APR2015	16:43	3	Double Read
					VISIT 11	28MAR2018	16:24	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22JAN2013	16:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S	4_5	Caudal Disc		VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S	4_5	Central Disc		Baseline	22JAN2013	16:04	N	Double Read
					VISIT 3A	22APR2013	15:57	N	Double Read
					VISIT 3K	25APR2013	16:34	N	Single Read
					VISIT 3L	15MAY2013	17:20	N	Single Read
					VISIT 4	06JUN2013	15:52	N	Double Read
					VISIT 5	31JUL2013	15:52	N	Double Read
					VISIT 6	15OCT2013	16:00	N	Double Read
					VISIT 7	09APR2014	16:14	N	Double Read
					VISIT 8	22APR2015	16:43	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22JAN2013	16:04	N	Double Read
					VISIT 3A	22APR2013	15:57	N	Double Read
					VISIT 3K	25APR2013	16:34	N	Single Read
					VISIT 3L	15MAY2013	17:20	N	Single Read
					VISIT 4	06JUN2013	15:52	N	Double Read
					VISIT 5	31JUL2013	15:52	N	Double Read
					VISIT 6	15OCT2013	16:00	N	Double Read
					VISIT 7	09APR2014	16:14	N	Double Read
					VISIT 8	22APR2015	16:43	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Caudal Disc)	5_S	4_5	Caudal Disc		VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
Dorsal disc extrusion (Central Disc)	5_S	4_5	Central Disc		Baseline	22JAN2013	16:04	Y	Double Read
					VISIT 3A	22APR2013	15:57	Y	Double Read
					VISIT 3K	25APR2013	16:34	Y	Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52	Y	Double Read
					VISIT 5	31JUL2013	15:52	Y	Double Read
					VISIT 6	15OCT2013	16:00	Y	Double Read
					VISIT 7	09APR2014	16:14	Y	Double Read
					VISIT 8	22APR2015	16:43	Y	Double Read
					VISIT 11	28MAR2018	16:24	Y	Double Read
Dorsal disc extrusion (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22JAN2013	16:04	N	Double Read
					VISIT 3A	22APR2013	15:57	Y	Double Read
					VISIT 3K	25APR2013	16:34	Y	Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52	Y	Double Read
					VISIT 5	31JUL2013	15:52	Y	Double Read
					VISIT 6	15OCT2013	16:00	Y	Double Read
					VISIT 7	09APR2014	16:14	N	Double Read
					VISIT 8	22APR2015	16:43	N	Double Read
					VISIT 11	28MAR2018	16:24	Y	Double Read
Extradiscal fluid collection	5_S	4_5	General		Baseline	22JAN2013	16:04	N	Double Read
					VISIT 3A	22APR2013	15:57	N	Double Read
					VISIT 3K	25APR2013	16:34	N	Single Read
					VISIT 3L	15MAY2013	17:20	N	Single Read
					VISIT 4	06JUN2013	15:52	N	Double Read
					VISIT 5	31JUL2013	15:52	N	Double Read
					VISIT 6	15OCT2013	16:00	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S	4_5	General		VISIT 7	09APR2014	16:14	N	Double Read
					VISIT 8	22APR2015	16:43	N	Double Read
					VISIT 11	28MAR2018	16:24	N	Double Read
Fracture	5_S	4_5	General		Baseline	22JAN2013	16:04	N	Double Read
					VISIT 3A	22APR2013	15:57	N	Double Read
					VISIT 3K	25APR2013	16:34	N	Single Read
					VISIT 3L	15MAY2013	17:20	N	Single Read
					VISIT 4	06JUN2013	15:52	N	Double Read
					VISIT 5	31JUL2013	15:52	N	Double Read
					VISIT 6	15OCT2013	16:00	N	Double Read
					VISIT 7	09APR2014	16:14	N	Double Read
					VISIT 8	22APR2015	16:43	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	22JAN2013	16:04	14.265	Double Read
					VISIT 3A	22APR2013	15:57	15.68	Double Read
					VISIT 3K	25APR2013	16:34	14.92	Single Read
					VISIT 3L	15MAY2013	17:20	12.93	Single Read
					VISIT 4	06JUN2013	15:52	13.945	Double Read
					VISIT 5	31JUL2013	15:52	13.375	Double Read
					VISIT 6	15OCT2013	16:00	11.815	Double Read
					VISIT 7	09APR2014	16:14	12.795	Double Read
					VISIT 8	22APR2015	16:43	14.055	Double Read
					VISIT 11	28MAR2018	16:24	11.11	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	22JAN2013	16:04	10.255	Double Read
					VISIT 3A	22APR2013	15:57	11.58	Double Read
					VISIT 3K	25APR2013	16:34	10.79	Single Read
					VISIT 3L	15MAY2013	17:20	10.89	Single Read
					VISIT 4	06JUN2013	15:52	11.85	Double Read
					VISIT 5	31JUL2013	15:52	12.235	Double Read
					VISIT 6	15OCT2013	16:00	11.36	Double Read
					VISIT 7	09APR2014	16:14	11.83	Double Read
					VISIT 8	22APR2015	16:43	12.035	Double Read
					VISIT 11	28MAR2018	16:24	11.12	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	22JAN2013	16:04	7.888565	Double Read
					VISIT 3A	22APR2013	15:57	7.63262	Double Read
					VISIT 3K	25APR2013	16:34	7.94937	Single Read
					VISIT 3L	15MAY2013	17:20	6.80448	Single Read
					VISIT 4	06JUN2013	15:52	7.991365	Double Read
					VISIT 5	31JUL2013	15:52	7.779735	Double Read
					VISIT 6	15OCT2013	16:00	7.349825	Double Read
					VISIT 7	09APR2014	16:14	7.329675	Double Read
					VISIT 8	22APR2015	16:43	7.416845	Double Read
					VISIT 11	28MAR2018	16:24	6.054625	Double Read
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	22JAN2013	16:04	7.438735	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	VISIT 3A	22APR2013	15:57	7.09476	Double Read
					VISIT 3K	25APR2013	16:34	7.599	Single Read
					VISIT 3L	15MAY2013	17:20	7.00257	Single Read
					VISIT 4	06JUN2013	15:52	7.632435	Double Read
					VISIT 5	31JUL2013	15:52	7.101745	Double Read
					VISIT 6	15OCT2013	16:00	7.70144	Double Read
					VISIT 7	09APR2014	16:14	7.494605	Double Read
					VISIT 8	22APR2015	16:43	7.664145	Double Read
					VISIT 11	28MAR2018	16:24	7.44083	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S	4_5	Central Disc		Baseline	22JAN2013	16:04	N	Double Read
					VISIT 3A	22APR2013	15:57	N	Double Read
					VISIT 3K	25APR2013	16:34	N	Single Read
					VISIT 3L	15MAY2013	17:20	N	Single Read
					VISIT 4	06JUN2013	15:52	N	Double Read
					VISIT 5	31JUL2013	15:52	N	Double Read
					VISIT 6	15OCT2013	16:00	N	Double Read
					VISIT 7	09APR2014	16:14	N	Double Read
					VISIT 8	22APR2015	16:43	N	Double Read
					VISIT 11	28MAR2018	16:24	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22JAN2013	16:04	N	Double Read
					VISIT 3A	22APR2013	15:57	N	Double Read
					VISIT 3K	25APR2013	16:34	N	Single Read
					VISIT 3L	15MAY2013	17:20	N	Single Read
					VISIT 4	06JUN2013	15:52	N	Double Read
					VISIT 5	31JUL2013	15:52	N	Double Read
					VISIT 6	15OCT2013	16:00	N	Double Read
					VISIT 7	09APR2014	16:14	N	Double Read
					VISIT 8	22APR2015	16:43	N	Double Read
					VISIT 11	28MAR2018	16:24	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S	4_5	Central Disc		Baseline	22JAN2013	16:04	N	Double Read
					VISIT 3A	22APR2013	15:57	N	Double Read
					VISIT 3K	25APR2013	16:34	N	Single Read
					VISIT 3L	15MAY2013	17:20	N	Single Read
					VISIT 4	06JUN2013	15:52	N	Double Read
					VISIT 5	31JUL2013	15:52	N	Double Read
					VISIT 6	15OCT2013	16:00	N	Double Read
					VISIT 7	09APR2014	16:14	N	Double Read
					VISIT 8	22APR2015	16:43	N	Double Read
					VISIT 11	28MAR2018	16:24	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22JAN2013	16:04	N	Double Read
					VISIT 3A	22APR2013	15:57	N	Double Read
					VISIT 3K	25APR2013	16:34	N	Single Read
					VISIT 3L	15MAY2013	17:20	N	Single Read
					VISIT 4	06JUN2013	15:52	N	Double Read
					VISIT 5	31JUL2013	15:52	N	Double Read
					VISIT 6	15OCT2013	16:00	N	Double Read
					VISIT 7	09APR2014	16:14	N	Double Read
					VISIT 8	22APR2015	16:43	N	Double Read
					VISIT 11	28MAR2018	16:24	N	Double Read
Normal lordotic LS	5_S	4_5	General		Baseline	22JAN2013	16:04	Y	Double Read
					VISIT 3A	22APR2013	15:57	Y	Double Read
					VISIT 3K	25APR2013	16:34	Y	Single Read
					VISIT 3L	15MAY2013	17:20	Y	Single Read
					VISIT 4	06JUN2013	15:52	Y	Double Read
					VISIT 5	31JUL2013	15:52	Y	Double Read
					VISIT 6	15OCT2013	16:00	Y	Double Read
					VISIT 7	09APR2014	16:14	Y	Double Read
					VISIT 8	22APR2015	16:43	Y	Double Read
					VISIT 11	28MAR2018	16:24	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S	4_5	Central Disc		Baseline	22JAN2013	16:04	1	Double Read
					VISIT 3A	22APR2013	15:57	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S	4_5	Central Disc		VISIT 3K	25APR2013	16:34	0	Single Read
					VISIT 3L	15MAY2013	17:20	0	Single Read
					VISIT 4	06JUN2013	15:52	1	Double Read
					VISIT 5	31JUL2013	15:52	2	Double Read
					VISIT 6	15OCT2013	16:00	0	Double Read
					VISIT 7	09APR2014	16:14	1	Double Read
					VISIT 8	22APR2015	16:43	2	Double Read
					VISIT 11	28MAR2018	16:24	1	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22JAN2013	16:04	0	Double Read
					VISIT 3A	22APR2013	15:57	0	Double Read
					VISIT 3K	25APR2013	16:34	0	Single Read
					VISIT 3L	15MAY2013	17:20	0	Single Read
					VISIT 4	06JUN2013	15:52	0	Double Read
					VISIT 5	31JUL2013	15:52	0	Double Read
					VISIT 6	15OCT2013	16:00	0	Double Read
					VISIT 7	09APR2014	16:14	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S	4_5	Caudal Disc		VISIT 8	22APR2015	16:43	0	Double Read
					VISIT 11	28MAR2018	16:24	0	Double Read
					Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
Protruding osteophyte (Central Disc)	5_S	4_5	Central Disc		VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
					Baseline	22JAN2013	16:04	N	Double Read
					VISIT 3A	22APR2013	15:57	N	Double Read
					VISIT 3K	25APR2013	16:34	N	Single Read
					VISIT 3L	15MAY2013	17:20	N	Single Read
					VISIT 4	06JUN2013	15:52	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S	4_5	Central Disc		VISIT 5	31JUL2013	15:52	N	Double Read
					VISIT 6	15OCT2013	16:00	N	Double Read
					VISIT 7	09APR2014	16:14	N	Double Read
					VISIT 8	22APR2015	16:43	N	Double Read
					VISIT 11	28MAR2018	16:24	N	Double Read
Protruding osteophyte (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22JAN2013	16:04	N	Double Read
					VISIT 3A	22APR2013	15:57	N	Double Read
					VISIT 3K	25APR2013	16:34	N	Single Read
					VISIT 3L	15MAY2013	17:20	N	Single Read
					VISIT 4	06JUN2013	15:52	N	Double Read
					VISIT 5	31JUL2013	15:52	N	Double Read
					VISIT 6	15OCT2013	16:00	N	Double Read
					VISIT 7	09APR2014	16:14	N	Double Read
					VISIT 8	22APR2015	16:43	N	Double Read
Relevant scoliosis	5_S	4_5	General		VISIT 11	28MAR2018	16:24	N	Double Read
					Baseline	22JAN2013	16:04	N	Double Read
					VISIT 3A	22APR2013	15:57	N	Double Read
					VISIT 3K	25APR2013	16:34	N	Single Read
					VISIT 3L	15MAY2013	17:20	N	Single Read
					VISIT 4	06JUN2013	15:52	N	Double Read
					VISIT 5	31JUL2013	15:52	N	Double Read
					VISIT 6	15OCT2013	16:00	N	Double Read
					VISIT 7	09APR2014	16:14	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S	4_5	Caudal Disc		VISIT 8	22APR2015	16:43	N	Double Read
					VISIT 11	28MAR2018	16:24	N	Double Read
					Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S	4_5	Caudal Disc		VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S	4_5	Central Disc		Baseline	22JAN2013	16:04	N	Double Read
					VISIT 3A	22APR2013	15:57	N	Double Read
					VISIT 3K	25APR2013	16:34	N	Single Read
					VISIT 3L	15MAY2013	17:20	Y	Single Read
					VISIT 4	06JUN2013	15:52	N	Double Read
					VISIT 5	31JUL2013	15:52	N	Double Read
					VISIT 6	15OCT2013	16:00	N	Double Read
					VISIT 7	09APR2014	16:14	N	Double Read
					VISIT 8	22APR2015	16:43	N	Double Read
					VISIT 11	28MAR2018	16:24	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22JAN2013	16:04	N	Double Read
					VISIT 3A	22APR2013	15:57	N	Double Read
					VISIT 3K	25APR2013	16:34	N	Single Read
					VISIT 3L	15MAY2013	17:20	Y	Single Read
					VISIT 4	06JUN2013	15:52	N	Double Read
					VISIT 5	31JUL2013	15:52	N	Double Read
					VISIT 6	15OCT2013	16:00	N	Double Read
					VISIT 7	09APR2014	16:14	N	Double Read
					VISIT 8	22APR2015	16:43	N	Double Read
					VISIT 11	28MAR2018	16:24	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	VISIT 11	28MAR2018	16:24		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	22JAN2013	16:04	80.9704	Double Read
					VISIT 3A	22APR2013	15:57	79.9792	Double Read
					VISIT 3K	25APR2013	16:34	85.13824	Single Read
					VISIT 3L	15MAY2013	17:20	79.14784	Single Read
					VISIT 4	06JUN2013	15:52	76.91408	Double Read
					VISIT 5	31JUL2013	15:52	85.28144	Double Read
					VISIT 6	15OCT2013	16:00	84.85584	Double Read
					VISIT 7	09APR2014	16:14	76.77808	Double Read
					VISIT 8	22APR2015	16:43	75.58016	Double Read
					VISIT 11	28MAR2018	16:24	75.56992	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
T2 (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
T2 (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	22JAN2013	16:04	75.82496	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	VISIT 3A	22APR2013	15:57	78.34048	Double Read
					VISIT 3K	25APR2013	16:34	78.99296	Single Read
					VISIT 3L	15MAY2013	17:20	82.82208	Single Read
					VISIT 4	06JUN2013	15:52	77.84928	Double Read
					VISIT 5	31JUL2013	15:52	86.70128	Double Read
					VISIT 6	15OCT2013	16:00	83.98144	Double Read
					VISIT 7	09APR2014	16:14	63.12112	Double Read
					VISIT 8	22APR2015	16:43	75.33808	Double Read
					VISIT 11	28MAR2018	16:24	73.81696	Double Read
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S	4_5	Central Disc		Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57	higher equal	Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57	equal equal	Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	22JAN2013	16:04	equal	Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	22JAN2013	16:04	equal	Double Read
					VISIT 3A	22APR2013	15:57	equal	Double Read
					VISIT 3K	25APR2013	16:34	higher	Single Read
					VISIT 3L	15MAY2013	17:20	equal	Single Read
					VISIT 4	06JUN2013	15:52	lower	Double Read
					VISIT 5	31JUL2013	15:52	equal	Double Read
					VISIT 6	15OCT2013	16:00	lower	Double Read
					VISIT 7	09APR2014	16:14	equal	Double Read
					VISIT 8	22APR2015	16:43	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	22JAN2013	16:04	equal	Double Read
					VISIT 3A	22APR2013	15:57	equal	Double Read
					VISIT 3K	25APR2013	16:34	equal	Single Read
					VISIT 3L	15MAY2013	17:20	lower	Single Read
					VISIT 4	06JUN2013	15:52	equal	Double Read
					VISIT 5	31JUL2013	15:52	equal	Double Read
					VISIT 6	15OCT2013	16:00	equal	Double Read
					VISIT 7	09APR2014	16:14	equal	Double Read
					VISIT 8	22APR2015	16:43	equal	Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24	equal	Double Read
					VISIT 11	28MAR2018	16:24	equal	Double Read
					VISIT 11	28MAR2018	16:24	equal	Double Read
					VISIT 11	28MAR2018	16:24	equal	Double Read
					VISIT 11	28MAR2018	16:24	equal	Double Read
					VISIT 11	28MAR2018	16:24	equal	Double Read
					VISIT 11	28MAR2018	16:24	equal	Double Read
					VISIT 11	28MAR2018	16:24	equal	Double Read
					VISIT 11	28MAR2018	16:24	equal	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S	4_5	Central Disc		Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34	higher	Single Read
					VISIT 3L	15MAY2013	17:20	equal	Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34	equal	Single Read
					VISIT 3L	15MAY2013	17:20	equal	Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	22JAN2013	16:04	8.01066077798	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	VISIT 3A	22APR2013	15:57	7.02759300153	Double Read
					VISIT 3K	25APR2013	16:34	2.39811109224	Single Read
					VISIT 3L	15MAY2013	17:20	7.82596228979	Single Read
					VISIT 4	06JUN2013	15:52	4.82584678104	Double Read
					VISIT 5	31JUL2013	15:52	8.39137081705	Double Read
					VISIT 6	15OCT2013	16:00	4.49889587226	Double Read
					VISIT 7	09APR2014	16:14	13.2765279429	Double Read
					VISIT 8	22APR2015	16:43	11.2348428741	Double Read
					VISIT 11	28MAR2018	16:24	7.40614914217	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	22JAN2013	16:04	5.8830168167	Double Read
					VISIT 3A	22APR2013	15:57	6.5332970952	Double Read
					VISIT 3K	25APR2013	16:34	9.8239103108	Single Read
					VISIT 3L	15MAY2013	17:20	6.9984712077	Single Read
					VISIT 4	06JUN2013	15:52	6.6975641243	Double Read
					VISIT 5	31JUL2013	15:52	6.5228469509	Double Read
					VISIT 6	15OCT2013	16:00	6.9376728384	Double Read
					VISIT 7	09APR2014	16:14	5.2392457958	Double Read
					VISIT 8	22APR2015	16:43	8.7430949549	Double Read
					VISIT 11	28MAR2018	16:24	8.6556072702	Double Read
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	22JAN2013	16:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	22JAN2013	16:04	9888.5	Double Read
					VISIT 3A	22APR2013	15:57	11002.0	Double Read
					VISIT 3K	25APR2013	16:34	11717	Single Read
					VISIT 3L	15MAY2013	17:20	10480	Single Read
					VISIT 4	06JUN2013	15:52	10438.5	Double Read
					VISIT 5	31JUL2013	15:52	10642.5	Double Read
					VISIT 6	15OCT2013	16:00	9302.5	Double Read
					VISIT 7	09APR2014	16:14	10708.0	Double Read
					VISIT 8	22APR2015	16:43	11106.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0110 Age=50 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	22JAN2013	16:04	11400.0	Double Read
					VISIT 3A	22APR2013	15:57	12462.5	Double Read
					VISIT 3K	25APR2013	16:34	12548	Single Read
					VISIT 3L	15MAY2013	17:20	10630	Single Read
					VISIT 4	06JUN2013	15:52	12413.0	Double Read
					VISIT 5	31JUL2013	15:52	11744.5	Double Read
					VISIT 6	15OCT2013	16:00	11171.5	Double Read
					VISIT 7	09APR2014	16:14	12103.0	Double Read
					VISIT 8	22APR2015	16:43	12592.0	Double Read
					VISIT 11	28MAR2018	16:24	10924.5	Double Read
Volume (mm^3) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	22JAN2013	16:04		Double Read
					VISIT 3A	22APR2013	15:57		Double Read
					VISIT 3K	25APR2013	16:34		Single Read
					VISIT 3L	15MAY2013	17:20		Single Read
					VISIT 4	06JUN2013	15:52		Double Read
					VISIT 5	31JUL2013	15:52		Double Read
					VISIT 6	15OCT2013	16:00		Double Read
					VISIT 7	09APR2014	16:14		Double Read
					VISIT 8	22APR2015	16:43		Double Read
					VISIT 11	28MAR2018	16:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	11MAR2013	15:57	3	Double Read
					VISIT 3A	10JUN2013	15:59	3	Double Read
					VISIT 3K	13JUN2013	16:48	4	Single Read
					VISIT 3L	02JUL2013	16:38	4	Single Read
					VISIT 4	25JUL2013	16:00	4	Double Read
					VISIT 5	04SEP2013	15:57	4	Double Read
					VISIT 6	18DEC2013	16:12	4	Double Read
					VISIT 7	04JUN2014	16:02	3	Double Read
					VISIT 8	10JUN2015	16:41	3	Double Read
					VISIT 11	30MAY2018	16:14	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAR2013	15:57	3	Double Read
					VISIT 3A	10JUN2013	15:59	3	Double Read
					VISIT 3K	13JUN2013	16:48	4	Single Read
					VISIT 3L	02JUL2013	16:38	4	Single Read
					VISIT 4	25JUL2013	16:00	3	Double Read
					VISIT 5	04SEP2013	15:57	3	Double Read
					VISIT 6	18DEC2013	16:12	3	Double Read
					VISIT 7	04JUN2014	16:02	3	Double Read
					VISIT 8	10JUN2015	16:41	3	Double Read
					VISIT 11	30MAY2018	16:14	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	11MAR2013	15:57		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	11MAR2013	15:57	N	Double Read
					VISIT 3A	10JUN2013	15:59	N	Double Read
					VISIT 3K	13JUN2013	16:48	N	Single Read
					VISIT 3L	02JUL2013	16:38	N	Single Read
					VISIT 4	25JUL2013	16:00	N	Double Read
					VISIT 5	04SEP2013	15:57	N	Double Read
					VISIT 6	18DEC2013	16:12	N	Double Read
					VISIT 7	04JUN2014	16:02	N	Double Read
					VISIT 8	10JUN2015	16:41	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAR2013	15:57	N	Double Read
					VISIT 3A	10JUN2013	15:59	N	Double Read
					VISIT 3K	13JUN2013	16:48	N	Single Read
					VISIT 3L	02JUL2013	16:38	Y	Single Read
					VISIT 4	25JUL2013	16:00	N	Double Read
					VISIT 5	04SEP2013	15:57	N	Double Read
					VISIT 6	18DEC2013	16:12	N	Double Read
					VISIT 7	04JUN2014	16:02	N	Double Read
					VISIT 8	10JUN2015	16:41	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	11MAR2013	15:57	Y	Double Read
					VISIT 3A	10JUN2013	15:59	N	Double Read
					VISIT 3K	13JUN2013	16:48	N	Single Read
					VISIT 3L	02JUL2013	16:38	Y	Single Read
					VISIT 4	25JUL2013	16:00	N	Double Read
					VISIT 5	04SEP2013	15:57	Y	Double Read
					VISIT 6	18DEC2013	16:12	Y	Double Read
					VISIT 7	04JUN2014	16:02	N	Double Read
					VISIT 8	10JUN2015	16:41	Y	Double Read
					VISIT 11	30MAY2018	16:14	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAR2013	15:57	N	Double Read
					VISIT 3A	10JUN2013	15:59	N	Double Read
					VISIT 3K	13JUN2013	16:48	N	Single Read
					VISIT 3L	02JUL2013	16:38	N	Single Read
					VISIT 4	25JUL2013	16:00	N	Double Read
					VISIT 5	04SEP2013	15:57	N	Double Read
					VISIT 6	18DEC2013	16:12	N	Double Read
					VISIT 7	04JUN2014	16:02	N	Double Read
					VISIT 8	10JUN2015	16:41	N	Double Read
					VISIT 11	30MAY2018	16:14	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	11MAR2013	15:57	N	Double Read
					VISIT 3A	10JUN2013	15:59	N	Double Read
					VISIT 3K	13JUN2013	16:48	N	Single Read
					VISIT 3L	02JUL2013	16:38	N	Single Read
					VISIT 4	25JUL2013	16:00	N	Double Read
					VISIT 5	04SEP2013	15:57	N	Double Read
					VISIT 6	18DEC2013	16:12	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 7	04JUN2014	16:02	N	Double Read
					VISIT 8	10JUN2015	16:41	N	Double Read
					VISIT 11	30MAY2018	16:14	N	Double Read
Fracture	5_S		General		Baseline	11MAR2013	15:57	N	Double Read
					VISIT 3A	10JUN2013	15:59	N	Double Read
					VISIT 3K	13JUN2013	16:48	N	Single Read
					VISIT 3L	02JUL2013	16:38	N	Single Read
					VISIT 4	25JUL2013	16:00	N	Double Read
					VISIT 5	04SEP2013	15:57	N	Double Read
					VISIT 6	18DEC2013	16:12	N	Double Read
					VISIT 7	04JUN2014	16:02	N	Double Read
					VISIT 8	10JUN2015	16:41	N	Double Read
					VISIT 11	30MAY2018	16:14	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11MAR2013	15:57	14.85	Double Read
					VISIT 3A	10JUN2013	15:59	15.905	Double Read
					VISIT 3K	13JUN2013	16:48	15.82	Single Read
					VISIT 3L	02JUL2013	16:38	16.60	Single Read
					VISIT 4	25JUL2013	16:00	15.355	Double Read
					VISIT 5	04SEP2013	15:57	14.54	Double Read
					VISIT 6	18DEC2013	16:12	14.41	Double Read
					VISIT 7	04JUN2014	16:02	14.915	Double Read
					VISIT 8	10JUN2015	16:41	13.71	Double Read
					VISIT 11	30MAY2018	16:14	15.455	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11MAR2013	15:57	17.565	Double Read
					VISIT 3A	10JUN2013	15:59	19.12	Double Read
					VISIT 3K	13JUN2013	16:48	19.01	Single Read
					VISIT 3L	02JUL2013	16:38	20.40	Single Read
					VISIT 4	25JUL2013	16:00	17.665	Double Read
					VISIT 5	04SEP2013	15:57	18.635	Double Read
					VISIT 6	18DEC2013	16:12	17.665	Double Read
					VISIT 7	04JUN2014	16:02	18.655	Double Read
					VISIT 8	10JUN2015	16:41	17.9	Double Read
					VISIT 11	30MAY2018	16:14	18.16	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11MAR2013	15:57	10.5653	Double Read
					VISIT 3A	10JUN2013	15:59	10.97695	Double Read
					VISIT 3K	13JUN2013	16:48	11.2354	Single Read
					VISIT 3L	02JUL2013	16:38	11.8346	Single Read
					VISIT 4	25JUL2013	16:00	10.40141	Double Read
					VISIT 5	04SEP2013	15:57	10.144035	Double Read
					VISIT 6	18DEC2013	16:12	9.88203	Double Read
					VISIT 7	04JUN2014	16:02	10.13162	Double Read
					VISIT 8	10JUN2015	16:41	10.788	Double Read
					VISIT 11	30MAY2018	16:14	10.10365	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11MAR2013	15:57	15.05975	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 3A	10JUN2013	15:59	16.58835	Double Read
					VISIT 3K	13JUN2013	16:48	16.4055	Single Read
					VISIT 3L	02JUL2013	16:38	16.8269	Single Read
					VISIT 4	25JUL2013	16:00	14.63955	Double Read
					VISIT 5	04SEP2013	15:57	15.60005	Double Read
					VISIT 6	18DEC2013	16:12	14.8898	Double Read
					VISIT 7	04JUN2014	16:02	15.0476	Double Read
					VISIT 8	10JUN2015	16:41	14.885	Double Read
					VISIT 11	30MAY2018	16:14	15.0651	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02	unknown	Double Read
					VISIT 8	10JUN2015	16:41		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	11MAR2013	15:57	N	Double Read
					VISIT 3A	10JUN2013	15:59	N	Double Read
					VISIT 3K	13JUN2013	16:48	N	Single Read
					VISIT 3L	02JUL2013	16:38	N	Single Read
					VISIT 4	25JUL2013	16:00	N	Double Read
					VISIT 5	04SEP2013	15:57	N	Double Read
					VISIT 6	18DEC2013	16:12	N	Double Read
					VISIT 7	04JUN2014	16:02	N	Double Read
					VISIT 8	10JUN2015	16:41	N	Double Read
					VISIT 11	30MAY2018	16:14	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAR2013	15:57	N	Double Read
					VISIT 3A	10JUN2013	15:59	N	Double Read
					VISIT 3K	13JUN2013	16:48	N	Single Read
					VISIT 3L	02JUL2013	16:38	N	Single Read
					VISIT 4	25JUL2013	16:00	N	Double Read
					VISIT 5	04SEP2013	15:57	N	Double Read
					VISIT 6	18DEC2013	16:12	N	Double Read
					VISIT 7	04JUN2014	16:02	N	Double Read
					VISIT 8	10JUN2015	16:41	N	Double Read
					VISIT 11	30MAY2018	16:14	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	11MAR2013	15:57	N	Double Read
					VISIT 3A	10JUN2013	15:59	N	Double Read
					VISIT 3K	13JUN2013	16:48	N	Single Read
					VISIT 3L	02JUL2013	16:38	N	Single Read
					VISIT 4	25JUL2013	16:00	N	Double Read
					VISIT 5	04SEP2013	15:57	N	Double Read
					VISIT 6	18DEC2013	16:12	N	Double Read
					VISIT 7	04JUN2014	16:02	N	Double Read
					VISIT 8	10JUN2015	16:41	N	Double Read
					VISIT 11	30MAY2018	16:14	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAR2013	15:57	N	Double Read
					VISIT 3A	10JUN2013	15:59	N	Double Read
					VISIT 3K	13JUN2013	16:48	N	Single Read
					VISIT 3L	02JUL2013	16:38	N	Single Read
					VISIT 4	25JUL2013	16:00	N	Double Read
					VISIT 5	04SEP2013	15:57	N	Double Read
					VISIT 6	18DEC2013	16:12	N	Double Read
					VISIT 7	04JUN2014	16:02	N	Double Read
					VISIT 8	10JUN2015	16:41	N	Double Read
					VISIT 11	30MAY2018	16:14	N	Double Read
Normal lordotic LS	5_S		General		Baseline	11MAR2013	15:57	Y	Double Read
					VISIT 3A	10JUN2013	15:59	Y	Double Read
					VISIT 3K	13JUN2013	16:48	Y	Single Read
					VISIT 3L	02JUL2013	16:38	Y	Single Read
					VISIT 4	25JUL2013	16:00	Y	Double Read
					VISIT 5	04SEP2013	15:57	Y	Double Read
					VISIT 6	18DEC2013	16:12	Y	Double Read
					VISIT 7	04JUN2014	16:02	Y	Double Read
					VISIT 8	10JUN2015	16:41	Y	Double Read
					VISIT 11	30MAY2018	16:14	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	11MAR2013	15:57	2	Double Read
					VISIT 3A	10JUN2013	15:59	2	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 3K	13JUN2013	16:48	0	Single Read
					VISIT 3L	02JUL2013	16:38	0	Single Read
					VISIT 4	25JUL2013	16:00	0	Double Read
					VISIT 5	04SEP2013	15:57	0	Double Read
					VISIT 6	18DEC2013	16:12	2	Double Read
					VISIT 7	04JUN2014	16:02	0	Double Read
					VISIT 8	10JUN2015	16:41	0	Double Read
					VISIT 11	30MAY2018	16:14	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAR2013	15:57	2	Double Read
					VISIT 3A	10JUN2013	15:59	2	Double Read
					VISIT 3K	13JUN2013	16:48	2	Single Read
					VISIT 3L	02JUL2013	16:38	2	Single Read
					VISIT 4	25JUL2013	16:00	2	Double Read
					VISIT 5	04SEP2013	15:57	2	Double Read
					VISIT 6	18DEC2013	16:12	2	Double Read
					VISIT 7	04JUN2014	16:02	2	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 8	10JUN2015	16:41	0	Double Read
					VISIT 11	30MAY2018	16:14	2	Double Read
					Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
					Baseline	11MAR2013	15:57	N	Double Read
					VISIT 3A	10JUN2013	15:59	N	Double Read
					VISIT 3K	13JUN2013	16:48	N	Single Read
					VISIT 3L	02JUL2013	16:38	N	Single Read
					VISIT 4	25JUL2013	16:00	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 5	04SEP2013	15:57	N	Double Read
					VISIT 6	18DEC2013	16:12	N	Double Read
					VISIT 7	04JUN2014	16:02	N	Double Read
					VISIT 8	10JUN2015	16:41	N	Double Read
					VISIT 11	30MAY2018	16:14	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAR2013	15:57	N	Double Read
					VISIT 3A	10JUN2013	15:59	N	Double Read
					VISIT 3K	13JUN2013	16:48	N	Single Read
					VISIT 3L	02JUL2013	16:38	N	Single Read
					VISIT 4	25JUL2013	16:00	N	Double Read
					VISIT 5	04SEP2013	15:57	N	Double Read
					VISIT 6	18DEC2013	16:12	N	Double Read
					VISIT 7	04JUN2014	16:02	N	Double Read
					VISIT 8	10JUN2015	16:41	N	Double Read
Relevant scoliosis	5_S		General		VISIT 11	30MAY2018	16:14	N	Double Read
					Baseline	11MAR2013	15:57	N	Double Read
					VISIT 3A	10JUN2013	15:59	N	Double Read
					VISIT 3K	13JUN2013	16:48	N	Single Read
					VISIT 3L	02JUL2013	16:38	N	Single Read
					VISIT 4	25JUL2013	16:00	N	Double Read
					VISIT 5	04SEP2013	15:57	N	Double Read
					VISIT 6	18DEC2013	16:12	N	Double Read
					VISIT 7	04JUN2014	16:02	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		VISIT 8	10JUN2015	16:41	N	Double Read
					VISIT 11	30MAY2018	16:14	N	Double Read
					Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	11MAR2013	15:57	N	Double Read
					VISIT 3A	10JUN2013	15:59	N	Double Read
					VISIT 3K	13JUN2013	16:48	N	Single Read
					VISIT 3L	02JUL2013	16:38	N	Single Read
					VISIT 4	25JUL2013	16:00	N	Double Read
					VISIT 5	04SEP2013	15:57	N	Double Read
					VISIT 6	18DEC2013	16:12	N	Double Read
					VISIT 7	04JUN2014	16:02	N	Double Read
					VISIT 8	10JUN2015	16:41	N	Double Read
					VISIT 11	30MAY2018	16:14	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAR2013	15:57	N	Double Read
					VISIT 3A	10JUN2013	15:59	N	Double Read
					VISIT 3K	13JUN2013	16:48	N	Single Read
					VISIT 3L	02JUL2013	16:38	N	Single Read
					VISIT 4	25JUL2013	16:00	N	Double Read
					VISIT 5	04SEP2013	15:57	N	Double Read
					VISIT 6	18DEC2013	16:12	N	Double Read
					VISIT 7	04JUN2014	16:02	N	Double Read
					VISIT 8	10JUN2015	16:41	N	Double Read
					VISIT 11	30MAY2018	16:14	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 11	30MAY2018	16:14		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11MAR2013	15:57	75.33392	Double Read
					VISIT 3A	10JUN2013	15:59	77.67376	Double Read
					VISIT 3K	13JUN2013	16:48	75.94176	Single Read
					VISIT 3L	02JUL2013	16:38	80.05472	Single Read
					VISIT 4	25JUL2013	16:00	81.27616	Double Read
					VISIT 5	04SEP2013	15:57	80.88544	Double Read
					VISIT 6	18DEC2013	16:12	63.93152	Double Read
					VISIT 7	04JUN2014	16:02	65.88896	Double Read
					VISIT 8	10JUN2015	16:41	67.1088	Double Read
					VISIT 11	30MAY2018	16:14	69.56032	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11MAR2013	15:57	78.14448	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 3A	10JUN2013	15:59	82.6664	Double Read
					VISIT 3K	13JUN2013	16:48	82.84256	Single Read
					VISIT 3L	02JUL2013	16:38	79.62816	Single Read
					VISIT 4	25JUL2013	16:00	83.79584	Double Read
					VISIT 5	04SEP2013	15:57	88.12064	Double Read
					VISIT 6	18DEC2013	16:12	66.60208	Double Read
					VISIT 7	04JUN2014	16:02	68.40544	Double Read
					VISIT 8	10JUN2015	16:41	69.99312	Double Read
					VISIT 11	30MAY2018	16:14	73.69216	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48	equal	Single Read
					VISIT 3L	02JUL2013	16:38	equal	Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48	equal	Single Read
					VISIT 3L	02JUL2013	16:38	equal	Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59	higher	Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	11MAR2013	15:57	lower	Double Read
					VISIT 3A	10JUN2013	15:59	equal	Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38	equal	Single Read
					VISIT 4	25JUL2013	16:00	equal	Double Read
					VISIT 5	04SEP2013	15:57	equal	Double Read
					VISIT 6	18DEC2013	16:12	equal	Double Read
					VISIT 7	04JUN2014	16:02	lower	Double Read
					VISIT 8	10JUN2015	16:41	lower	Double Read
					VISIT 11	30MAY2018	16:14	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12	equal	Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59	higher equal	Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59	equal equal	Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11MAR2013	15:57	5.00414472567	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	10JUN2013	15:59	7.49617801936	Double Read
					VISIT 3K	13JUN2013	16:48	6.96631900798	Single Read
					VISIT 3L	02JUL2013	16:38	5.43570579242	Single Read
					VISIT 4	25JUL2013	16:00	7.00464752845	Double Read
					VISIT 5	04SEP2013	15:57	5.98177679633	Double Read
					VISIT 6	18DEC2013	16:12	7.50346186512	Double Read
					VISIT 7	04JUN2014	16:02	7.71011381009	Double Read
					VISIT 8	10JUN2015	16:41	7.10470528282	Double Read
					VISIT 11	30MAY2018	16:14	8.39806352981	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11MAR2013	15:57	7.9412264311	Double Read
					VISIT 3A	10JUN2013	15:59	9.1279497197	Double Read
					VISIT 3K	13JUN2013	16:48	8.2721929675	Single Read
					VISIT 3L	02JUL2013	16:38	6.9738338712	Single Read
					VISIT 4	25JUL2013	16:00	7.5347647358	Double Read
					VISIT 5	04SEP2013	15:57	7.6577271955	Double Read
					VISIT 6	18DEC2013	16:12	7.8966740275	Double Read
					VISIT 7	04JUN2014	16:02	8.0303380329	Double Read
					VISIT 8	10JUN2015	16:41	9.9836589094	Double Read
					VISIT 11	30MAY2018	16:14	8.5870086631	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	11MAR2013	15:57		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
Volume (mm ³) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11MAR2013	15:57	16491.0	Double Read
					VISIT 3A	10JUN2013	15:59	18177.5	Double Read
					VISIT 3K	13JUN2013	16:48	17793	Single Read
					VISIT 3L	02JUL2013	16:38	18141	Single Read
					VISIT 4	25JUL2013	16:00	17694.5	Double Read
					VISIT 5	04SEP2013	15:57	17320.5	Double Read
					VISIT 6	18DEC2013	16:12	16643.0	Double Read
					VISIT 7	04JUN2014	16:02	17322.0	Double Read
					VISIT 8	10JUN2015	16:41	16383.0	Double Read
Volume (mm ³) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
Volume (mm ³) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0111 Age=52 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11MAR2013	15:57	27656.0	Double Read
					VISIT 3A	10JUN2013	15:59	28741.5	Double Read
					VISIT 3K	13JUN2013	16:48	27603	Single Read
					VISIT 3L	02JUL2013	16:38	28785	Single Read
					VISIT 4	25JUL2013	16:00	26078.0	Double Read
					VISIT 5	04SEP2013	15:57	28011.5	Double Read
					VISIT 6	18DEC2013	16:12	27424.5	Double Read
					VISIT 7	04JUN2014	16:02	27049.5	Double Read
					VISIT 8	10JUN2015	16:41	26237.0	Double Read
					VISIT 11	30MAY2018	16:14	24746.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	11MAR2013	15:57		Double Read
					VISIT 3A	10JUN2013	15:59		Double Read
					VISIT 3K	13JUN2013	16:48		Single Read
					VISIT 3L	02JUL2013	16:38		Single Read
					VISIT 4	25JUL2013	16:00		Double Read
					VISIT 5	04SEP2013	15:57		Double Read
					VISIT 6	18DEC2013	16:12		Double Read
					VISIT 7	04JUN2014	16:02		Double Read
					VISIT 8	10JUN2015	16:41		Double Read
					VISIT 11	30MAY2018	16:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0112 Age=26 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	25MAR2013	16:17	4	Single Read
					VISIT 11	08JUL2013	16:15	3	Single Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25MAR2013	16:17	4	Single Read
					VISIT 11	08JUL2013	16:15	4	Single Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	25MAR2013	16:17	N	Single Read
					VISIT 11	08JUL2013	16:15	N	Single Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25MAR2013	16:17	N	Single Read
					VISIT 11	08JUL2013	16:15	N	Single Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	25MAR2013	16:17	Y	Single Read
					VISIT 11	08JUL2013	16:15	N	Single Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25MAR2013	16:17	N	Single Read
					VISIT 11	08JUL2013	16:15	N	Single Read
Extradiscal fluid collection	5_S		General		Baseline	25MAR2013	16:17	N	Single Read
					VISIT 11	08JUL2013	16:15	N	Single Read
Fracture	5_S		General		Baseline	25MAR2013	16:17	N	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0112 Age=26 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Fracture	5_S		General		VISIT 11	08JUL2013	16:15	N	Single Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25MAR2013	16:17	14.72	Single Read
					VISIT 11	08JUL2013	16:15	10.63	Single Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25MAR2013	16:17	13.75	Single Read
					VISIT 11	08JUL2013	16:15	12.46	Single Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25MAR2013	16:17	10.4406	Single Read
					VISIT 11	08JUL2013	16:15	8.32253	Single Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25MAR2013	16:17	11.102	Single Read
					VISIT 11	08JUL2013	16:15	10.5496	Single Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	25MAR2013	16:17	N	Single Read
					VISIT 11	08JUL2013	16:15	N	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0112 Age=26 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25MAR2013	16:17	N	Single Read
					VISIT 11	08JUL2013	16:15	N	Single Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	25MAR2013	16:17	N	Single Read
					VISIT 11	08JUL2013	16:15	N	Single Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25MAR2013	16:17	N	Single Read
					VISIT 11	08JUL2013	16:15	N	Single Read
Normal lordotic LS	5_S		General		Baseline	25MAR2013	16:17	Y	Single Read
					VISIT 11	08JUL2013	16:15	Y	Single Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	25MAR2013	16:17	0	Single Read
					VISIT 11	08JUL2013	16:15	0	Single Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25MAR2013	16:17	0	Single Read
					VISIT 11	08JUL2013	16:15	0	Single Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	25MAR2013	16:17	N	Single Read
					VISIT 11	08JUL2013	16:15	N	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0112 Age=26 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25MAR2013	16:17	N	Single Read
					VISIT 11	08JUL2013	16:15	N	Single Read
Relevant scoliosis	5_S		General		Baseline	25MAR2013	16:17	N	Single Read
					VISIT 11	08JUL2013	16:15	N	Single Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	25MAR2013	16:17	N	Single Read
					VISIT 11	08JUL2013	16:15	N	Single Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25MAR2013	16:17	N	Single Read
					VISIT 11	08JUL2013	16:15	N	Single Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15	113.12768	Single Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25MAR2013	16:17	72.21312	Single Read
					VISIT 11	08JUL2013	16:15	109.32608	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0112 Age=26 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15	119.01536	Single Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25MAR2013	16:17	73.91872	Single Read
					VISIT 11	08JUL2013	16:15	78.71264	Single Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0112 Age=26 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	25MAR2013	16:17	lower	Single Read
					VISIT 11	08JUL2013	16:15	higher	Single Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15	higher	Single Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15	equal	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0112 Age=26 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15	42.159334126	Single Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25MAR2013	16:17	7.8114489553	Single Read
					VISIT 11	08JUL2013	16:15	15.287922541	Single Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15	2.3781212841	Single Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25MAR2013	16:17	6.7452216748	Single Read
					VISIT 11	08JUL2013	16:15	5.7114319687	Single Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0112 Age=26 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15	7039	Single Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25MAR2013	16:17	12894	Single Read
					VISIT 11	08JUL2013	16:15	9269	Single Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15	2230	Single Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25MAR2013	16:17	14120	Single Read
					VISIT 11	08JUL2013	16:15	13648	Single Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	25MAR2013	16:17		Single Read
					VISIT 11	08JUL2013	16:15		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	22MAY2013	17:09	4	Double Read
					VISIT 3A	05AUG2013	16:09	3	Double Read
					VISIT 3K	09AUG2013	16:30	4	Single Read
					VISIT 3L	28AUG2013	16:45	4	Single Read
					VISIT 4	10SEP2013	15:55	3	Double Read
					VISIT 5	06NOV2013	16:30	4	Double Read
					VISIT 6	28JAN2014	16:31	4	Double Read
					VISIT 7	30JUL2014	16:21	3	Double Read
					VISIT 11	17OCT2018	16:21	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22MAY2013	17:09	2	Double Read
					VISIT 3A	05AUG2013	16:09	2	Double Read
					VISIT 3K	09AUG2013	16:30	3	Single Read
					VISIT 3L	28AUG2013	16:45	3	Single Read
					VISIT 4	10SEP2013	15:55	2	Double Read
					VISIT 5	06NOV2013	16:30	3	Double Read
					VISIT 6	28JAN2014	16:31	2	Double Read
					VISIT 7	30JUL2014	16:21	2	Double Read
					VISIT 11	17OCT2018	16:21	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	22MAY2013	17:09	N	Double Read
					VISIT 3A	05AUG2013	16:09	N	Double Read
					VISIT 3K	09AUG2013	16:30	N	Single Read
					VISIT 3L	28AUG2013	16:45	N	Single Read
					VISIT 4	10SEP2013	15:55	N	Double Read
					VISIT 5	06NOV2013	16:30	N	Double Read
					VISIT 6	28JAN2014	16:31	N	Double Read
					VISIT 7	30JUL2014	16:21	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22MAY2013	17:09	N	Double Read
					VISIT 3A	05AUG2013	16:09	N	Double Read
					VISIT 3K	09AUG2013	16:30	N	Single Read
					VISIT 3L	28AUG2013	16:45	N	Single Read
					VISIT 4	10SEP2013	15:55	N	Double Read
					VISIT 5	06NOV2013	16:30	N	Double Read
					VISIT 6	28JAN2014	16:31	N	Double Read
					VISIT 7	30JUL2014	16:21	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	17OCT2018	16:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	22MAY2013	17:09	Y	Double Read
					VISIT 3A	05AUG2013	16:09	Y	Double Read
					VISIT 3K	09AUG2013	16:30	N	Single Read
					VISIT 3L	28AUG2013	16:45	Y	Single Read
					VISIT 4	10SEP2013	15:55	Y	Double Read
					VISIT 5	06NOV2013	16:30	Y	Double Read
					VISIT 6	28JAN2014	16:31	Y	Double Read
					VISIT 7	30JUL2014	16:21	Y	Double Read
					VISIT 11	17OCT2018	16:21	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22MAY2013	17:09	N	Double Read
					VISIT 3A	05AUG2013	16:09	N	Double Read
					VISIT 3K	09AUG2013	16:30	N	Single Read
					VISIT 3L	28AUG2013	16:45	N	Single Read
					VISIT 4	10SEP2013	15:55	N	Double Read
					VISIT 5	06NOV2013	16:30	N	Double Read
					VISIT 6	28JAN2014	16:31	N	Double Read
					VISIT 7	30JUL2014	16:21	N	Double Read
					VISIT 11	17OCT2018	16:21	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	22MAY2013	17:09	N	Double Read
					VISIT 3A	05AUG2013	16:09	N	Double Read
					VISIT 3K	09AUG2013	16:30	N	Single Read
					VISIT 3L	28AUG2013	16:45	N	Single Read
					VISIT 4	10SEP2013	15:55	N	Double Read
					VISIT 5	06NOV2013	16:30	N	Double Read
					VISIT 6	28JAN2014	16:31	N	Double Read
					VISIT 7	30JUL2014	16:21	N	Double Read
					VISIT 11	17OCT2018	16:21	N	Double Read
Fracture	5_S		General		Baseline	22MAY2013	17:09	N	Double Read
					VISIT 3A	05AUG2013	16:09	N	Double Read
					VISIT 3K	09AUG2013	16:30	N	Single Read
					VISIT 3L	28AUG2013	16:45	N	Single Read
					VISIT 4	10SEP2013	15:55	N	Double Read
					VISIT 5	06NOV2013	16:30	N	Double Read
					VISIT 6	28JAN2014	16:31	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Fracture	5_S		General		VISIT 7	30JUL2014	16:21	N	Double Read
					VISIT 11	17OCT2018	16:21	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22MAY2013	17:09	18.18	Double Read
					VISIT 3A	05AUG2013	16:09	17.54	Double Read
					VISIT 3K	09AUG2013	16:30	16.50	Single Read
					VISIT 3L	28AUG2013	16:45	15.81	Single Read
					VISIT 4	10SEP2013	15:55	18.375	Double Read
					VISIT 5	06NOV2013	16:30	17.47	Double Read
					VISIT 6	28JAN2014	16:31	16.33	Double Read
					VISIT 7	30JUL2014	16:21	19.075	Double Read
					VISIT 11	17OCT2018	16:21		Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22MAY2013	17:09	18.205	Double Read
					VISIT 3A	05AUG2013	16:09	18.245	Double Read
					VISIT 3K	09AUG2013	16:30	18.43	Single Read
					VISIT 3L	28AUG2013	16:45	17.48	Single Read
					VISIT 4	10SEP2013	15:55	17.86	Double Read
					VISIT 5	06NOV2013	16:30	17.455	Double Read
					VISIT 6	28JAN2014	16:31	18.41	Double Read
					VISIT 7	30JUL2014	16:21	18.285	Double Read
					VISIT 11	17OCT2018	16:21		Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22MAY2013	17:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22MAY2013	17:09	11.32805	Double Read
					VISIT 3A	05AUG2013	16:09	10.59734	Double Read
					VISIT 3K	09AUG2013	16:30	11.7984	Single Read
					VISIT 3L	28AUG2013	16:45	11.6017	Single Read
					VISIT 4	10SEP2013	15:55	11.6782	Double Read
					VISIT 5	06NOV2013	16:30	10.65713	Double Read
					VISIT 6	28JAN2014	16:31	9.922515	Double Read
					VISIT 7	30JUL2014	16:21	8.899195	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22MAY2013	17:09	13.41735	Double Read
					VISIT 3A	05AUG2013	16:09	12.58465	Double Read
					VISIT 3K	09AUG2013	16:30	14.3371	Single Read
					VISIT 3L	28AUG2013	16:45	13.5685	Single Read
					VISIT 4	10SEP2013	15:55	13.2752	Double Read
					VISIT 5	06NOV2013	16:30	13.0301	Double Read
					VISIT 6	28JAN2014	16:31	13.5291	Double Read
					VISIT 7	30JUL2014	16:21	13.8924	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	22MAY2013	17:09	N	Double Read
					VISIT 3A	05AUG2013	16:09	N	Double Read
					VISIT 3K	09AUG2013	16:30	N	Single Read
					VISIT 3L	28AUG2013	16:45	N	Single Read
					VISIT 4	10SEP2013	15:55	N	Double Read
					VISIT 5	06NOV2013	16:30	N	Double Read
					VISIT 6	28JAN2014	16:31	Y	Double Read
					VISIT 7	30JUL2014	16:21	N	Double Read
					VISIT 11	17OCT2018	16:21	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22MAY2013	17:09	N	Double Read
					VISIT 3A	05AUG2013	16:09	N	Double Read
					VISIT 3K	09AUG2013	16:30	N	Single Read
					VISIT 3L	28AUG2013	16:45	N	Single Read
					VISIT 4	10SEP2013	15:55	N	Double Read
					VISIT 5	06NOV2013	16:30	N	Double Read
					VISIT 6	28JAN2014	16:31	N	Double Read
					VISIT 7	30JUL2014	16:21	N	Double Read
					VISIT 11	17OCT2018	16:21	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	22MAY2013	17:09	N	Double Read
					VISIT 3A	05AUG2013	16:09	N	Double Read
					VISIT 3K	09AUG2013	16:30	N	Single Read
					VISIT 3L	28AUG2013	16:45	N	Single Read
					VISIT 4	10SEP2013	15:55	N	Double Read
					VISIT 5	06NOV2013	16:30	N	Double Read
					VISIT 6	28JAN2014	16:31	N	Double Read
					VISIT 7	30JUL2014	16:21	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 11	17OCT2018	16:21	N	Double Read
					Baseline	22MAY2013	17:09	N	Double Read
					VISIT 3A	05AUG2013	16:09	N	Double Read
					VISIT 3K	09AUG2013	16:30	N	Single Read
					VISIT 3L	28AUG2013	16:45	N	Single Read
					VISIT 4	10SEP2013	15:55	N	Double Read
					VISIT 5	06NOV2013	16:30	N	Double Read
					VISIT 6	28JAN2014	16:31	N	Double Read
Normal lordotic LS	5_S		General		VISIT 7	30JUL2014	16:21	N	Double Read
					VISIT 11	17OCT2018	16:21	N	Double Read
					Baseline	22MAY2013	17:09	Y	Double Read
					VISIT 3A	05AUG2013	16:09	Y	Double Read
					VISIT 3K	09AUG2013	16:30	Y	Single Read
					VISIT 3L	28AUG2013	16:45	Y	Single Read
					VISIT 4	10SEP2013	15:55	Y	Double Read
					VISIT 5	06NOV2013	16:30	Y	Double Read
					VISIT 6	28JAN2014	16:31	Y	Double Read
					VISIT 7	30JUL2014	16:21	Y	Double Read
					VISIT 11	17OCT2018	16:21	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	22MAY2013	17:09	0	Double Read
					VISIT 3A	05AUG2013	16:09	0	Double Read
					VISIT 3K	09AUG2013	16:30	0	Single Read
					VISIT 3L	28AUG2013	16:45	0	Single Read
					VISIT 4	10SEP2013	15:55	0	Double Read
					VISIT 5	06NOV2013	16:30	1	Double Read
					VISIT 6	28JAN2014	16:31	1	Double Read
					VISIT 7	30JUL2014	16:21	1	Double Read
					VISIT 11	17OCT2018	16:21	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22MAY2013	17:09	0	Double Read
					VISIT 3A	05AUG2013	16:09	0	Double Read
					VISIT 3K	09AUG2013	16:30	0	Single Read
					VISIT 3L	28AUG2013	16:45	0	Single Read
					VISIT 4	10SEP2013	15:55	0	Double Read
					VISIT 5	06NOV2013	16:30	0	Double Read
					VISIT 6	28JAN2014	16:31	0	Double Read
					VISIT 7	30JUL2014	16:21	0	Double Read
					VISIT 11	17OCT2018	16:21	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	22MAY2013	17:09	N	Double Read
					VISIT 3A	05AUG2013	16:09	N	Double Read
					VISIT 3K	09AUG2013	16:30	N	Single Read
					VISIT 3L	28AUG2013	16:45	N	Single Read
					VISIT 4	10SEP2013	15:55	N	Double Read
					VISIT 5	06NOV2013	16:30	N	Double Read
					VISIT 6	28JAN2014	16:31	N	Double Read
					VISIT 7	30JUL2014	16:21	N	Double Read
					VISIT 11	17OCT2018	16:21	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22MAY2013	17:09	N	Double Read
					VISIT 3A	05AUG2013	16:09	N	Double Read
					VISIT 3K	09AUG2013	16:30	N	Single Read
					VISIT 3L	28AUG2013	16:45	N	Single Read
					VISIT 4	10SEP2013	15:55	N	Double Read
					VISIT 5	06NOV2013	16:30	N	Double Read
					VISIT 6	28JAN2014	16:31	N	Double Read
					VISIT 7	30JUL2014	16:21	N	Double Read
					VISIT 11	17OCT2018	16:21	N	Double Read
Relevant scoliosis	5_S		General		Baseline	22MAY2013	17:09	N	Double Read
					VISIT 3A	05AUG2013	16:09	N	Double Read
					VISIT 3K	09AUG2013	16:30	N	Single Read
					VISIT 3L	28AUG2013	16:45	N	Single Read
					VISIT 4	10SEP2013	15:55	N	Double Read
					VISIT 5	06NOV2013	16:30	N	Double Read
					VISIT 6	28JAN2014	16:31	N	Double Read
					VISIT 7	30JUL2014	16:21	N	Double Read
					VISIT 11	17OCT2018	16:21	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	22MAY2013	17:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	22MAY2013	17:09	N	Double Read
					VISIT 3A	05AUG2013	16:09	N	Double Read
					VISIT 3K	09AUG2013	16:30	N	Single Read
					VISIT 3L	28AUG2013	16:45	N	Single Read
					VISIT 4	10SEP2013	15:55	N	Double Read
					VISIT 5	06NOV2013	16:30	N	Double Read
					VISIT 6	28JAN2014	16:31	N	Double Read
					VISIT 7	30JUL2014	16:21	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22MAY2013	17:09	N	Double Read
					VISIT 3A	05AUG2013	16:09	N	Double Read
					VISIT 3K	09AUG2013	16:30	N	Single Read
					VISIT 3L	28AUG2013	16:45	N	Single Read
					VISIT 4	10SEP2013	15:55	N	Double Read
					VISIT 5	06NOV2013	16:30	N	Double Read
					VISIT 6	28JAN2014	16:31	N	Double Read
					VISIT 7	30JUL2014	16:21	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22MAY2013	17:09	88.97728	Double Read
					VISIT 3A	05AUG2013	16:09	78.57712	Double Read
					VISIT 3K	09AUG2013	16:30	82.09696	Single Read
					VISIT 3L	28AUG2013	16:45	83.16992	Single Read
					VISIT 4	10SEP2013	15:55	83.93504	Double Read
					VISIT 5	06NOV2013	16:30	84.43872	Double Read
					VISIT 6	28JAN2014	16:31	67.49136	Double Read
					VISIT 7	30JUL2014	16:21	64.2232	Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30	112.51584	Single Read
					VISIT 3L	28AUG2013	16:45	107.96864	Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22MAY2013	17:09	94.42544	Double Read
					VISIT 3A	05AUG2013	16:09	92.668	Double Read
					VISIT 3K	09AUG2013	16:30	91.11168	Single Read
					VISIT 3L	28AUG2013	16:45	91.47552	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 4	10SEP2013	15:55	94.7968	Double Read
					VISIT 5	06NOV2013	16:30	94.42912	Double Read
					VISIT 6	28JAN2014	16:31	80.20016	Double Read
					VISIT 7	30JUL2014	16:21	84.75664	Double Read
					VISIT 11	17OCT2018	16:21	84.54576	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30	90.39232	Single Read
					VISIT 3L	28AUG2013	16:45	91.9184	Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30	equal	Single Read
					VISIT 3L	28AUG2013	16:45	equal	Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30	equal	Single Read
					VISIT 3L	28AUG2013	16:45	equal	Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	22MAY2013	17:09	lower	Double Read
					VISIT 3A	05AUG2013	16:09	lower	Double Read
					VISIT 3K	09AUG2013	16:30	lower	Single Read
					VISIT 3L	28AUG2013	16:45	lower	Single Read
					VISIT 4	10SEP2013	15:55	lower	Double Read
					VISIT 5	06NOV2013	16:30	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		VISIT 6	28JAN2014	16:31	lower	Double Read
					VISIT 7	30JUL2014	16:21	lower	Double Read
					VISIT 11	17OCT2018	16:21	higher	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30	equal	Single Read
					VISIT 3L	28AUG2013	16:45	equal	Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 11	17OCT2018	16:21		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30	equal	Single Read
					VISIT 3L	28AUG2013	16:45	equal	Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22MAY2013	17:09	6.5228469509	Double Read
					VISIT 3A	05AUG2013	16:09	6.3350772889	Double Read
					VISIT 3K	09AUG2013	16:30	10.248574825	Single Read
					VISIT 3L	28AUG2013	16:45	8.0241345337	Single Read
					VISIT 4	10SEP2013	15:55	5.7592593850	Double Read
					VISIT 5	06NOV2013	16:30	5.8090028877	Double Read
					VISIT 6	28JAN2014	16:31	8.0497570918	Double Read
					VISIT 7	30JUL2014	16:21	8.7867029047	Double Read
					VISIT 11	17OCT2018	16:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30	38.91843044	Single Read
					VISIT 3L	28AUG2013	16:45	27.9786648548	Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22MAY2013	17:09	9.4634143027	Double Read
					VISIT 3A	05AUG2013	16:09	10.0948802446	Double Read
					VISIT 3K	09AUG2013	16:30	8.12742653304	Single Read
					VISIT 3L	28AUG2013	16:45	6.01810090029	Single Read
					VISIT 4	10SEP2013	15:55	6.52197044335	Double Read
					VISIT 5	06NOV2013	16:30	8.85729233906	Double Read
					VISIT 6	28JAN2014	16:31	9.25612366228	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 7	30JUL2014	16:21	3.57850857822	Double Read
					VISIT 11	17OCT2018	16:21	14.8207915746	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30	7.49880074741	Single Read
					VISIT 3L	28AUG2013	16:45	6.28503482249	Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 11	17OCT2018	16:21		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22MAY2013	17:09	21030.0	Double Read
					VISIT 3A	05AUG2013	16:09	19390.5	Double Read
					VISIT 3K	09AUG2013	16:30	19598	Single Read
					VISIT 3L	28AUG2013	16:45	17211	Single Read
					VISIT 4	10SEP2013	15:55	21759.0	Double Read
					VISIT 5	06NOV2013	16:30	17992.5	Double Read
					VISIT 6	28JAN2014	16:31	18142.0	Double Read
					VISIT 7	30JUL2014	16:21	18180.5	Double Read
					VISIT 11	17OCT2018	16:21		Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	22MAY2013	17:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30		Single Read
					VISIT 3L	28AUG2013	16:45		Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read
Volume (mm ³) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30	10312	Single Read
					VISIT 3L	28AUG2013	16:45	15082	Single Read
					VISIT 4	10SEP2013	15:55		Double Read
					VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
Volume (mm ³) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22MAY2013	17:09	27426.0	Double Read
					VISIT 3A	05AUG2013	16:09	28116.5	Double Read
					VISIT 3K	09AUG2013	16:30	27881	Single Read
					VISIT 3L	28AUG2013	16:45	26056	Single Read
					VISIT 4	10SEP2013	15:55	27872.0	Double Read
					VISIT 5	06NOV2013	16:30	27594.5	Double Read
					VISIT 6	28JAN2014	16:31	27658.0	Double Read
					VISIT 7	30JUL2014	16:21	27731.5	Double Read
Volume (mm ³) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	22MAY2013	17:09		Double Read
					VISIT 3A	05AUG2013	16:09		Double Read
					VISIT 3K	09AUG2013	16:30	17569	Single Read
					VISIT 3L	28AUG2013	16:45	10974	Single Read
					VISIT 4	10SEP2013	15:55		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0113 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 5	06NOV2013	16:30		Double Read
					VISIT 6	28JAN2014	16:31		Double Read
					VISIT 7	30JUL2014	16:21		Double Read
					VISIT 11	17OCT2018	16:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	10JUN2013	12:16	2	Double Read
					VISIT 3A	10SEP2013	17:04	2	Double Read
					VISIT 3K	13SEP2013	16:27	2	Single Read
					VISIT 3L	01OCT2013	16:26	2	Single Read
					VISIT 4	16OCT2013	16:39	2	Double Read
					VISIT 5	10DEC2013	16:16	2	Double Read
					VISIT 6	12MAR2014	16:33	2	Double Read
					VISIT 7	10SEP2014	15:57	2	Double Read
					VISIT 8	09SEP2015	16:02	2	Double Read
					VISIT 11	05SEP2018	13:47	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	10JUN2013	12:16	3	Double Read
					VISIT 3A	10SEP2013	17:04	4	Double Read
					VISIT 3K	13SEP2013	16:27	4	Single Read
					VISIT 3L	01OCT2013	16:26	4	Single Read
					VISIT 4	16OCT2013	16:39	3	Double Read
					VISIT 5	10DEC2013	16:16	3	Double Read
					VISIT 6	12MAR2014	16:33	4	Double Read
					VISIT 7	10SEP2014	15:57	4	Double Read
					VISIT 8	09SEP2015	16:02	3	Double Read
					VISIT 11	05SEP2018	13:47	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	10JUN2013	12:16	3	Double Read
					VISIT 3A	10SEP2013	17:04	4	Double Read
					VISIT 3K	13SEP2013	16:27	4	Single Read
					VISIT 3L	01OCT2013	16:26	4	Single Read
					VISIT 4	16OCT2013	16:39	3	Double Read
					VISIT 5	10DEC2013	16:16	3	Double Read
					VISIT 6	12MAR2014	16:33	3	Double Read
					VISIT 7	10SEP2014	15:57	3	Double Read
					VISIT 8	09SEP2015	16:02	3	Double Read
					VISIT 11	05SEP2018	13:47	4	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	10JUN2013	12:16	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
					VISIT 8	09SEP2015	16:02	N	Double Read
					VISIT 11	05SEP2018	13:47	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
					VISIT 8	09SEP2015	16:02	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
					VISIT 8	09SEP2015	16:02	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
					VISIT 8	09SEP2015	16:02	N	Double Read
					VISIT 11	05SEP2018	13:47	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	10JUN2013	12:16	Y	Double Read
					VISIT 3A	16OCT2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	Y	Single Read
					VISIT 3L	01OCT2013	16:26	Y	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	Y	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
					VISIT 8	09SEP2015	16:02	N	Double Read
					VISIT 11	05SEP2018	13:47	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
					VISIT 8	09SEP2015	16:02	N	Double Read
					VISIT 11	05SEP2018	13:47	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	4_5		General		VISIT 7	10SEP2014	15:57	N	Double Read
					VISIT 8	09SEP2015	16:02	N	Double Read
					VISIT 11	05SEP2018	13:47	N	Double Read
Fracture	4_5		General		Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
					VISIT 8	09SEP2015	16:02	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	10JUN2013	12:16	15.83	Double Read
					VISIT 3A	10SEP2013	17:04	16.22	Double Read
					VISIT 3K	13SEP2013	16:27	13.30	Single Read
					VISIT 3L	01OCT2013	16:26	15.23	Single Read
					VISIT 4	16OCT2013	16:39	16.36	Double Read
					VISIT 5	10DEC2013	16:16	16.32	Double Read
					VISIT 6	12MAR2014	16:33	14.56	Double Read
					VISIT 7	10SEP2014	15:57	16.755	Double Read
					VISIT 8	09SEP2015	16:02	15.975	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	10JUN2013	12:16	13.31	Double Read
					VISIT 3A	10SEP2013	17:04	13.105	Double Read
					VISIT 3K	13SEP2013	16:27	11.92	Single Read
					VISIT 3L	01OCT2013	16:26	11.94	Single Read
					VISIT 4	16OCT2013	16:39	11.555	Double Read
					VISIT 5	10DEC2013	16:16	13.525	Double Read
					VISIT 6	12MAR2014	16:33	13.395	Double Read
					VISIT 7	10SEP2014	15:57	13.18	Double Read
					VISIT 8	09SEP2015	16:02	12.655	Double Read
					VISIT 11	05SEP2018	13:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	10JUN2013	12:16	17.04	Double Read
					VISIT 3A	10SEP2013	17:04	13.37	Double Read
					VISIT 3K	13SEP2013	16:27	12.03	Single Read
					VISIT 3L	01OCT2013	16:26	12.59	Single Read
					VISIT 4	16OCT2013	16:39	12.45	Double Read
					VISIT 5	10DEC2013	16:16	29.13	Double Read
					VISIT 6	12MAR2014	16:33	13.65	Double Read
					VISIT 7	10SEP2014	15:57	13.735	Double Read
					VISIT 8	09SEP2015	16:02	12.265	Double Read
					VISIT 11	05SEP2018	13:47		Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	10JUN2013	12:16	10.9391	Double Read
					VISIT 3A	10SEP2013	17:04	11.06185	Double Read
					VISIT 3K	13SEP2013	16:27	10.9925	Single Read
					VISIT 3L	01OCT2013	16:26	10.4245	Single Read
					VISIT 4	16OCT2013	16:39	10.48955	Double Read
					VISIT 5	10DEC2013	16:16	9.822005	Double Read
					VISIT 6	12MAR2014	16:33	9.943435	Double Read
					VISIT 7	10SEP2014	15:57	9.96676	Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47	9.159375	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	10JUN2013	12:16	9.331435	Double Read
					VISIT 3A	10SEP2013	17:04	9.29953	Double Read
					VISIT 3K	13SEP2013	16:27	9.40401	Single Read
					VISIT 3L	01OCT2013	16:26	9.40393	Single Read
					VISIT 4	16OCT2013	16:39	8.57348	Double Read
					VISIT 5	10DEC2013	16:16	9.15068	Double Read
					VISIT 6	12MAR2014	16:33	8.67533	Double Read
					VISIT 7	10SEP2014	15:57	8.85221	Double Read
					VISIT 8	09SEP2015	16:02	8.54458	Double Read
					VISIT 11	05SEP2018	13:47	8.69239	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	10JUN2013	12:16	10.7736	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	VISIT 3A	10SEP2013	17:04	9.890225	Double Read
					VISIT 3K	13SEP2013	16:27	10.3945	Single Read
					VISIT 3L	01OCT2013	16:26	9.82674	Single Read
					VISIT 4	16OCT2013	16:39	9.50884	Double Read
					VISIT 5	10DEC2013	16:16	10.53556	Double Read
					VISIT 6	12MAR2014	16:33	10.45443	Double Read
					VISIT 7	10SEP2014	15:57	10.789625	Double Read
					VISIT 8	09SEP2015	16:02	9.756635	Double Read
					VISIT 11	05SEP2018	13:47	10.040425	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
					VISIT 8	09SEP2015	16:02	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
					VISIT 8	09SEP2015	16:02	N	Double Read
					VISIT 11	05SEP2018	13:47	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
					VISIT 8	09SEP2015	16:02	N	Double Read
					VISIT 11	05SEP2018	13:47	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
					VISIT 8	09SEP2015	16:02	N	Double Read
					VISIT 11	05SEP2018	13:47	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
					VISIT 8	09SEP2015	16:02	N	Double Read
					VISIT 11	05SEP2018	13:47	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
					VISIT 8	09SEP2015	16:02	N	Double Read
					VISIT 11	05SEP2018	13:47	N	Double Read
Normal lordotic LS	4_5		General		Baseline	10JUN2013	12:16	Y	Double Read
					VISIT 3A	10SEP2013	17:04	Y	Double Read
					VISIT 3K	13SEP2013	16:27	Y	Single Read
					VISIT 3L	01OCT2013	16:26	Y	Single Read
					VISIT 4	16OCT2013	16:39	Y	Double Read
					VISIT 5	10DEC2013	16:16	Y	Double Read
					VISIT 6	12MAR2014	16:33	Y	Double Read
					VISIT 7	10SEP2014	15:57	Y	Double Read
					VISIT 8	09SEP2015	16:02	Y	Double Read
					VISIT 11	05SEP2018	13:47	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	10JUN2013	12:16	0	Double Read
					VISIT 3A	10SEP2013	17:04	0	Double Read
					VISIT 3K	13SEP2013	16:27	0	Single Read
					VISIT 3L	01OCT2013	16:26	0	Single Read
					VISIT 4	16OCT2013	16:39	0	Double Read
					VISIT 5	10DEC2013	16:16	0	Double Read
					VISIT 6	12MAR2014	16:33	0	Double Read
					VISIT 7	10SEP2014	15:57	0	Double Read
					VISIT 8	09SEP2015	16:02	0	Double Read
					VISIT 11	05SEP2018	13:47	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	10JUN2013	12:16	0	Double Read
					VISIT 3A	10SEP2013	17:04	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 3K	13SEP2013	16:27	0	Single Read
					VISIT 3L	01OCT2013	16:26	0	Single Read
					VISIT 4	16OCT2013	16:39	0	Double Read
					VISIT 5	10DEC2013	16:16	0	Double Read
					VISIT 6	12MAR2014	16:33	0	Double Read
					VISIT 7	10SEP2014	15:57	0	Double Read
					VISIT 8	09SEP2015	16:02	0	Double Read
					VISIT 11	05SEP2018	13:47	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	10JUN2013	12:16	0	Double Read
					VISIT 3A	10SEP2013	17:04	0	Double Read
					VISIT 3K	13SEP2013	16:27	0	Single Read
					VISIT 3L	01OCT2013	16:26	0	Single Read
					VISIT 4	16OCT2013	16:39	0	Double Read
					VISIT 5	10DEC2013	16:16	0	Double Read
					VISIT 6	12MAR2014	16:33	0	Double Read
					VISIT 7	10SEP2014	15:57	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
					VISIT 8	09SEP2015	16:02	N	Double Read
					VISIT 11	05SEP2018	13:47	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
					VISIT 8	09SEP2015	16:02	N	Double Read
Relevant scoliosis	4_5		General		VISIT 11	05SEP2018	13:47	N	Double Read
					Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		VISIT 8	09SEP2015	16:02	N	Double Read
					VISIT 11	05SEP2018	13:47	N	Double Read
					Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		VISIT 8	09SEP2015	16:02	N	Double Read
					VISIT 11	05SEP2018	13:47	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
					VISIT 8	09SEP2015	16:02	N	Double Read
					VISIT 11	05SEP2018	13:47	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	10JUN2013	12:16	N	Double Read
					VISIT 3A	10SEP2013	17:04	N	Double Read
					VISIT 3K	13SEP2013	16:27	N	Single Read
					VISIT 3L	01OCT2013	16:26	N	Single Read
					VISIT 4	16OCT2013	16:39	N	Double Read
					VISIT 5	10DEC2013	16:16	N	Double Read
					VISIT 6	12MAR2014	16:33	N	Double Read
					VISIT 7	10SEP2014	15:57	N	Double Read
					VISIT 8	09SEP2015	16:02	N	Double Read
					VISIT 11	05SEP2018	13:47	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27	100.38784	Single Read
					VISIT 3L	01OCT2013	16:26	113.71776	Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 11	05SEP2018	13:47		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	10JUN2013	12:16	115.7208	Double Read
					VISIT 3A	10SEP2013	17:04	115.55392	Double Read
					VISIT 3K	13SEP2013	16:27	118.6144	Single Read
					VISIT 3L	01OCT2013	16:26	121.01824	Single Read
					VISIT 4	16OCT2013	16:39	111.14464	Double Read
					VISIT 5	10DEC2013	16:16	106.10736	Double Read
					VISIT 6	12MAR2014	16:33	113.996	Double Read
					VISIT 7	10SEP2014	15:57	100.1336	Double Read
					VISIT 8	09SEP2015	16:02	106.25808	Double Read
					VISIT 11	05SEP2018	13:47	91.76608	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27	126.22784	Single Read
					VISIT 3L	01OCT2013	16:26	121.87328	Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27		Single Read
					VISIT 3L	01OCT2013	16:26		Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	10JUN2013	12:16	77.67744	Double Read
					VISIT 3A	10SEP2013	17:04	85.40032	Double Read
					VISIT 3K	13SEP2013	16:27	74.26112	Single Read
					VISIT 3L	01OCT2013	16:26	89.72064	Single Read
					VISIT 4	16OCT2013	16:39	89.52528	Double Read
					VISIT 5	10DEC2013	16:16	66.31776	Double Read
					VISIT 6	12MAR2014	16:33	68.4184	Double Read
					VISIT 7	10SEP2014	15:57	68.18416	Double Read
					VISIT 8	09SEP2015	16:02	75.33824	Double Read
					VISIT 11	05SEP2018	13:47	71.48624	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27		Single Read
					VISIT 3L	01OCT2013	16:26		Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27		Single Read
					VISIT 3L	01OCT2013	16:26		Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	10JUN2013	12:16	83.51632	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	VISIT 3A	10SEP2013	17:04	81.5792	Double Read
					VISIT 3K	13SEP2013	16:27	74.54272	Single Read
					VISIT 3L	01OCT2013	16:26	86.2688	Single Read
					VISIT 4	16OCT2013	16:39	86.7304	Double Read
					VISIT 5	10DEC2013	16:16	70.52944	Double Read
					VISIT 6	12MAR2014	16:33	70.53648	Double Read
					VISIT 7	10SEP2014	15:57	68.77072	Double Read
					VISIT 8	09SEP2015	16:02	79.69696	Double Read
					VISIT 11	05SEP2018	13:47	65.20768	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27		Single Read
					VISIT 3L	01OCT2013	16:26		Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27	equal	Single Read
					VISIT 3L	01OCT2013	16:26	equal	Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27	equal	Single Read
					VISIT 3L	01OCT2013	16:26	equal	Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27	equal	Single Read
					VISIT 3L	01OCT2013	16:26	equal	Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27		Single Read
					VISIT 3L	01OCT2013	16:26		Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	10JUN2013	12:16	lower	Double Read
					VISIT 3A	10SEP2013	17:04	lower	Double Read
					VISIT 3K	13SEP2013	16:27	lower	Single Read
					VISIT 3L	01OCT2013	16:26	lower	Single Read
					VISIT 4	16OCT2013	16:39	lower	Double Read
					VISIT 5	10DEC2013	16:16	equal	Double Read
					VISIT 6	12MAR2014	16:33	lower	Double Read
					VISIT 7	10SEP2014	15:57	lower	Double Read
					VISIT 8	09SEP2015	16:02	lower	Double Read
					VISIT 11	05SEP2018	13:47	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27		Single Read
					VISIT 3L	01OCT2013	16:26		Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27		Single Read
					VISIT 3L	01OCT2013	16:26		Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	10JUN2013	12:16	equal	Double Read
					VISIT 3A	10SEP2013	17:04	equal	Double Read
					VISIT 3K	13SEP2013	16:27	equal	Single Read
					VISIT 3L	01OCT2013	16:26	equal	Single Read
					VISIT 4	16OCT2013	16:39	equal	Double Read
					VISIT 5	10DEC2013	16:16	equal	Double Read
					VISIT 6	12MAR2014	16:33	lower	Double Read
					VISIT 7	10SEP2014	15:57	lower	Double Read
					VISIT 8	09SEP2015	16:02	equal	Double Read
					VISIT 11	05SEP2018	13:47	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27		Single Read
					VISIT 3L	01OCT2013	16:26		Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27	equal	Single Read
					VISIT 3L	01OCT2013	16:26	equal	Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27	equal	Single Read
					VISIT 3L	01OCT2013	16:26	equal	Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27	equal	Single Read
					VISIT 3L	01OCT2013	16:26	equal	Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27	1.5287922541	Single Read
					VISIT 3L	01OCT2013	16:26	45.799218617	Single Read
					VISIT 4	16OCT2013	16:39	2	Double Read
					VISIT 5	10DEC2013	16:16	3	Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	10JUN2013	12:16	6.4209274673	Double Read
					VISIT 3A	10SEP2013	17:04	2.3243281807	Double Read
					VISIT 3K	13SEP2013	16:27	19.1219976213	Single Read
					VISIT 3L	01OCT2013	16:26	9.18892474945	Single Read
					VISIT 4	16OCT2013	16:39	9.40129777476	Double Read
					VISIT 5	10DEC2013	16:16	5.60557159843	Double Read
					VISIT 6	12MAR2014	16:33	6.34166128758	Double Read
					VISIT 7	10SEP2014	15:57	5.22242908103	Double Read
					VISIT 8	09SEP2015	16:02	9.90883641923	Double Read
					VISIT 11	05SEP2018	13:47	5.25370477323	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27	15.8541871921	Single Read
					VISIT 3L	01OCT2013	16:26	7.88177339901	Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	VISIT 3K	13SEP2013	16:27		Single Read
					VISIT 3L	01OCT2013	16:26		Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	10JUN2013	12:16	10.5222422287	Double Read
					VISIT 3A	10SEP2013	17:04	6.30556820113	Double Read
					VISIT 3K	13SEP2013	16:27	10.5229692543	Single Read
					VISIT 3L	01OCT2013	16:26	6.4810327841	Single Read
					VISIT 4	16OCT2013	16:39	8.86699507388	Double Read
					VISIT 5	10DEC2013	16:16	6.40097842705	Double Read
					VISIT 6	12MAR2014	16:33	6.68631900799	Double Read
					VISIT 7	10SEP2014	15:57	8.62080516392	Double Read
					VISIT 8	09SEP2015	16:02	4.15928656361	Double Read
					VISIT 11	05SEP2018	13:47	5.8462170885	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27		Single Read
					VISIT 3L	01OCT2013	16:26		Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27		Single Read
					VISIT 3L	01OCT2013	16:26		Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	10JUN2013	12:16	3.6414540513	Double Read
					VISIT 3A	10SEP2013	17:04	10.3834890437	Double Read
					VISIT 3K	13SEP2013	16:27	8.49329030066	Single Read
					VISIT 3L	01OCT2013	16:26	9.67426533039	Single Read
					VISIT 4	16OCT2013	16:39	7.27232206557	Double Read
					VISIT 5	10DEC2013	16:16	8.09380669271	Double Read
					VISIT 6	12MAR2014	16:33	8.94626804824	Double Read
					VISIT 7	10SEP2014	15:57	6.85691863428	Double Read
					VISIT 8	09SEP2015	16:02	4.77511805673	Double Read
					VISIT 11	05SEP2018	13:47	6.34812977748	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27		Single Read
					VISIT 3L	01OCT2013	16:26		Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27	8152	Single Read
					VISIT 3L	01OCT2013	16:26	8832	Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	10JUN2013	12:16	12800.5	Double Read
					VISIT 3A	10SEP2013	17:04	13117.0	Double Read
					VISIT 3K	13SEP2013	16:27	12948	Single Read
					VISIT 3L	01OCT2013	16:26	13747	Single Read
					VISIT 4	16OCT2013	16:39	12357.5	Double Read
					VISIT 5	10DEC2013	16:16	12641.0	Double Read
					VISIT 6	12MAR2014	16:33	12284.5	Double Read
					VISIT 7	10SEP2014	15:57	12549.0	Double Read
					VISIT 8	09SEP2015	16:02	12137.0	Double Read
					VISIT 11	05SEP2018	13:47		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	10JUN2013	12:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27	4796	Single Read
					VISIT 3L	01OCT2013	16:26	4915	Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read
Volume (mm ³) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27		Single Read
					VISIT 3L	01OCT2013	16:26		Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
Volume (mm ³) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	10JUN2013	12:16	14910.0	Double Read
					VISIT 3A	10SEP2013	17:04	14304.0	Double Read
					VISIT 3K	13SEP2013	16:27	13558	Single Read
					VISIT 3L	01OCT2013	16:26	13843	Single Read
					VISIT 4	16OCT2013	16:39	12709.0	Double Read
					VISIT 5	10DEC2013	16:16	14268.0	Double Read
					VISIT 6	12MAR2014	16:33	15062.0	Double Read
					VISIT 7	10SEP2014	15:57	13875.5	Double Read
					VISIT 8	09SEP2015	16:02	13790.5	Double Read
Volume (mm ³) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 3K	13SEP2013	16:27		Single Read
					VISIT 3L	01OCT2013	16:26		Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27		Single Read
					VISIT 3L	01OCT2013	16:26		Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	10JUN2013	12:16	16621.0	Double Read
					VISIT 3A	10SEP2013	17:04	15659.0	Double Read
					VISIT 3K	13SEP2013	16:27	14628	Single Read
					VISIT 3L	01OCT2013	16:26	15859	Single Read
					VISIT 4	16OCT2013	16:39	14181.5	Double Read
					VISIT 5	10DEC2013	16:16	15568.0	Double Read
					VISIT 6	12MAR2014	16:33	14720.5	Double Read
					VISIT 7	10SEP2014	15:57	15613.5	Double Read
					VISIT 8	09SEP2015	16:02	15765.5	Double Read
					VISIT 11	05SEP2018	13:47		Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	10JUN2013	12:16		Double Read
					VISIT 3A	10SEP2013	17:04		Double Read
					VISIT 3K	13SEP2013	16:27		Single Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0114 Age=36 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 3L	01OCT2013	16:26		Single Read
					VISIT 4	16OCT2013	16:39		Double Read
					VISIT 5	10DEC2013	16:16		Double Read
					VISIT 6	12MAR2014	16:33		Double Read
					VISIT 7	10SEP2014	15:57		Double Read
					VISIT 8	09SEP2015	16:02		Double Read
					VISIT 11	05SEP2018	13:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	11JUN2013	16:00	3	Double Read
					VISIT 3A	16SEP2013	13:15	4	Double Read
					VISIT 3K	19SEP2013	16:33	4	Single Read
					VISIT 3L	08OCT2013	17:08	4	Single Read
					VISIT 4	30OCT2013	16:42	3	Double Read
					VISIT 5	17DEC2013	16:32	4	Double Read
					VISIT 6	11MAR2014	16:49	4	Double Read
					VISIT 7	25SEP2014	16:20	4	Double Read
					VISIT 8	16SEP2015	15:31	3	Double Read
					VISIT 11	10OCT2018	16:18	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11JUN2013	16:00	3	Double Read
					VISIT 3A	16SEP2013	13:15	3	Double Read
					VISIT 3K	19SEP2013	16:33	4	Single Read
					VISIT 3L	08OCT2013	17:08	4	Single Read
					VISIT 4	30OCT2013	16:42	3	Double Read
					VISIT 5	17DEC2013	16:32	3	Double Read
					VISIT 6	11MAR2014	16:49	3	Double Read
					VISIT 7	25SEP2014	16:20	3	Double Read
					VISIT 8	16SEP2015	15:31	3	Double Read
					VISIT 11	10OCT2018	16:18	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	11JUN2013	16:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31	N	Double Read
					VISIT 11	10OCT2018	16:18		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	11JUN2013	16:00	N	Double Read
					VISIT 3A	16SEP2013	13:15	N	Double Read
					VISIT 3K	19SEP2013	16:33	N	Single Read
					VISIT 3L	08OCT2013	17:08	N	Single Read
					VISIT 4	30OCT2013	16:42	N	Double Read
					VISIT 5	17DEC2013	16:32	N	Double Read
					VISIT 6	11MAR2014	16:49	N	Double Read
					VISIT 7	25SEP2014	16:20	N	Double Read
					VISIT 8	16SEP2015	15:31	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11JUN2013	16:00	N	Double Read
					VISIT 3A	16SEP2013	13:15	N	Double Read
					VISIT 3K	19SEP2013	16:33	N	Single Read
					VISIT 3L	08OCT2013	17:08	N	Single Read
					VISIT 4	30OCT2013	16:42	N	Double Read
					VISIT 5	17DEC2013	16:32	N	Double Read
					VISIT 6	11MAR2014	16:49	N	Double Read
					VISIT 7	25SEP2014	16:20	N	Double Read
					VISIT 8	16SEP2015	15:31	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31	N	Double Read
					VISIT 11	10OCT2018	16:18		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	11JUN2013	16:00	Y	Double Read
					VISIT 3A	16SEP2013	13:15	N	Double Read
					VISIT 3K	19SEP2013	16:33	Y	Single Read
					VISIT 3L	08OCT2013	17:08	Y	Single Read
					VISIT 4	30OCT2013	16:42	N	Double Read
					VISIT 5	17DEC2013	16:32	Y	Double Read
					VISIT 6	11MAR2014	16:49	Y	Double Read
					VISIT 7	25SEP2014	16:20	Y	Double Read
					VISIT 8	16SEP2015	15:31	N	Double Read
					VISIT 11	10OCT2018	16:18	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11JUN2013	16:00	N	Double Read
					VISIT 3A	16SEP2013	13:15	N	Double Read
					VISIT 3K	19SEP2013	16:33	N	Single Read
					VISIT 3L	08OCT2013	17:08	N	Single Read
					VISIT 4	30OCT2013	16:42	N	Double Read
					VISIT 5	17DEC2013	16:32	N	Double Read
					VISIT 6	11MAR2014	16:49	N	Double Read
					VISIT 7	25SEP2014	16:20	N	Double Read
					VISIT 8	16SEP2015	15:31	N	Double Read
					VISIT 11	10OCT2018	16:18	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	11JUN2013	16:00	N	Double Read
					VISIT 3A	16SEP2013	13:15	N	Double Read
					VISIT 3K	19SEP2013	16:33	N	Single Read
					VISIT 3L	08OCT2013	17:08	N	Single Read
					VISIT 4	30OCT2013	16:42	N	Double Read
					VISIT 5	17DEC2013	16:32	N	Double Read
					VISIT 6	11MAR2014	16:49	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 7	25SEP2014	16:20	N	Double Read
					VISIT 8	16SEP2015	15:31	N	Double Read
					VISIT 11	10OCT2018	16:18	N	Double Read
Fracture	5_S		General		Baseline	11JUN2013	16:00	N	Double Read
					VISIT 3A	16SEP2013	13:15	N	Double Read
					VISIT 3K	19SEP2013	16:33	N	Single Read
					VISIT 3L	08OCT2013	17:08	N	Single Read
					VISIT 4	30OCT2013	16:42	N	Double Read
					VISIT 5	17DEC2013	16:32	N	Double Read
					VISIT 6	11MAR2014	16:49	N	Double Read
					VISIT 7	25SEP2014	16:20	N	Double Read
					VISIT 8	16SEP2015	15:31	N	Double Read
					VISIT 11	10OCT2018	16:18	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11JUN2013	16:00	15.39	Double Read
					VISIT 3A	16SEP2013	13:15	17.245	Double Read
					VISIT 3K	19SEP2013	16:33	16.87	Single Read
					VISIT 3L	08OCT2013	17:08	15.73	Single Read
					VISIT 4	30OCT2013	16:42	16.06	Double Read
					VISIT 5	17DEC2013	16:32	13.92	Double Read
					VISIT 6	11MAR2014	16:49	15.3	Double Read
					VISIT 7	25SEP2014	16:20	15.865	Double Read
					VISIT 8	16SEP2015	15:31	15.905	Double Read
					VISIT 11	10OCT2018	16:18	13.685	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11JUN2013	16:00	15.615	Double Read
					VISIT 3A	16SEP2013	13:15	16.485	Double Read
					VISIT 3K	19SEP2013	16:33	16.13	Single Read
					VISIT 3L	08OCT2013	17:08	15.65	Single Read
					VISIT 4	30OCT2013	16:42	16.33	Double Read
					VISIT 5	17DEC2013	16:32	14.75	Double Read
					VISIT 6	11MAR2014	16:49	15.435	Double Read
					VISIT 7	25SEP2014	16:20	15.895	Double Read
					VISIT 8	16SEP2015	15:31	16.76	Double Read
					VISIT 11	10OCT2018	16:18	15.03	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11JUN2013	16:00	8.523575	Double Read
					VISIT 3A	16SEP2013	13:15	9.08495	Double Read
					VISIT 3K	19SEP2013	16:33	9.56145	Single Read
					VISIT 3L	08OCT2013	17:08	8.96686	Single Read
					VISIT 4	30OCT2013	16:42	8.748115	Double Read
					VISIT 5	17DEC2013	16:32	8.28087	Double Read
					VISIT 6	11MAR2014	16:49	8.6693	Double Read
					VISIT 7	25SEP2014	16:20	8.78966	Double Read
					VISIT 8	16SEP2015	15:31	8.513055	Double Read
					VISIT 11	10OCT2018	16:18	7.932915	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11JUN2013	16:00	11.97685	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 3A	16SEP2013	13:15	12.50915	Double Read
					VISIT 3K	19SEP2013	16:33	13.4452	Single Read
					VISIT 3L	08OCT2013	17:08	12.149	Single Read
					VISIT 4	30OCT2013	16:42	12.18635	Double Read
					VISIT 5	17DEC2013	16:32	12.789	Double Read
					VISIT 6	11MAR2014	16:49	12.7131	Double Read
					VISIT 7	25SEP2014	16:20	11.9724	Double Read
					VISIT 8	16SEP2015	15:31	11.5823	Double Read
					VISIT 11	10OCT2018	16:18	12.5073	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	11JUN2013	16:00	N	Double Read
					VISIT 3A	16SEP2013	13:15	N	Double Read
					VISIT 3K	19SEP2013	16:33	N	Single Read
					VISIT 3L	08OCT2013	17:08	N	Single Read
					VISIT 4	30OCT2013	16:42	N	Double Read
					VISIT 5	17DEC2013	16:32	N	Double Read
					VISIT 6	11MAR2014	16:49	N	Double Read
					VISIT 7	25SEP2014	16:20	N	Double Read
					VISIT 8	16SEP2015	15:31	N	Double Read
					VISIT 11	10OCT2018	16:18	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11JUN2013	16:00	N	Double Read
					VISIT 3A	16SEP2013	13:15	N	Double Read
					VISIT 3K	19SEP2013	16:33	N	Single Read
					VISIT 3L	08OCT2013	17:08	N	Single Read
					VISIT 4	30OCT2013	16:42	N	Double Read
					VISIT 5	17DEC2013	16:32	N	Double Read
					VISIT 6	11MAR2014	16:49	N	Double Read
					VISIT 7	25SEP2014	16:20	N	Double Read
					VISIT 8	16SEP2015	15:31	N	Double Read
					VISIT 11	10OCT2018	16:18	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	11JUN2013	16:00	N	Double Read
					VISIT 3A	16SEP2013	13:15	N	Double Read
					VISIT 3K	19SEP2013	16:33	N	Single Read
					VISIT 3L	08OCT2013	17:08	N	Single Read
					VISIT 4	30OCT2013	16:42	N	Double Read
					VISIT 5	17DEC2013	16:32	N	Double Read
					VISIT 6	11MAR2014	16:49	N	Double Read
					VISIT 7	25SEP2014	16:20	N	Double Read
					VISIT 8	16SEP2015	15:31	N	Double Read
					VISIT 11	10OCT2018	16:18	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11JUN2013	16:00	N	Double Read
					VISIT 3A	16SEP2013	13:15	N	Double Read
					VISIT 3K	19SEP2013	16:33	N	Single Read
					VISIT 3L	08OCT2013	17:08	N	Single Read
					VISIT 4	30OCT2013	16:42	N	Double Read
					VISIT 5	17DEC2013	16:32	N	Double Read
					VISIT 6	11MAR2014	16:49	N	Double Read
					VISIT 7	25SEP2014	16:20	N	Double Read
					VISIT 8	16SEP2015	15:31	N	Double Read
					VISIT 11	10OCT2018	16:18	N	Double Read
Normal lordotic LS	5_S		General		Baseline	11JUN2013	16:00	Y	Double Read
					VISIT 3A	16SEP2013	13:15	Y	Double Read
					VISIT 3K	19SEP2013	16:33	Y	Single Read
					VISIT 3L	08OCT2013	17:08	Y	Single Read
					VISIT 4	30OCT2013	16:42	Y	Double Read
					VISIT 5	17DEC2013	16:32	Y	Double Read
					VISIT 6	11MAR2014	16:49	Y	Double Read
					VISIT 7	25SEP2014	16:20	Y	Double Read
					VISIT 8	16SEP2015	15:31	Y	Double Read
					VISIT 11	10OCT2018	16:18	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	11JUN2013	16:00	0	Double Read
					VISIT 3A	16SEP2013	13:15	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 3K	19SEP2013	16:33	0	Single Read
					VISIT 3L	08OCT2013	17:08	0	Single Read
					VISIT 4	30OCT2013	16:42	0	Double Read
					VISIT 5	17DEC2013	16:32	0	Double Read
					VISIT 6	11MAR2014	16:49	0	Double Read
					VISIT 7	25SEP2014	16:20	0	Double Read
					VISIT 8	16SEP2015	15:31	2	Double Read
					VISIT 11	10OCT2018	16:18	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11JUN2013	16:00	0	Double Read
					VISIT 3A	16SEP2013	13:15	0	Double Read
					VISIT 3K	19SEP2013	16:33	0	Single Read
					VISIT 3L	08OCT2013	17:08	0	Single Read
					VISIT 4	30OCT2013	16:42	0	Double Read
					VISIT 5	17DEC2013	16:32	0	Double Read
					VISIT 6	11MAR2014	16:49	0	Double Read
					VISIT 7	25SEP2014	16:20	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 8	16SEP2015	15:31	0	Double Read
					VISIT 11	10OCT2018	16:18	0	Double Read
					Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31	N	Double Read
					VISIT 11	10OCT2018	16:18		Double Read
					Baseline	11JUN2013	16:00	N	Double Read
					VISIT 3A	16SEP2013	13:15	N	Double Read
					VISIT 3K	19SEP2013	16:33	N	Single Read
					VISIT 3L	08OCT2013	17:08	N	Single Read
					VISIT 4	30OCT2013	16:42	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 5	17DEC2013	16:32	N	Double Read
					VISIT 6	11MAR2014	16:49	N	Double Read
					VISIT 7	25SEP2014	16:20	N	Double Read
					VISIT 8	16SEP2015	15:31	N	Double Read
					VISIT 11	10OCT2018	16:18	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11JUN2013	16:00	N	Double Read
					VISIT 3A	16SEP2013	13:15	N	Double Read
					VISIT 3K	19SEP2013	16:33	N	Single Read
					VISIT 3L	08OCT2013	17:08	N	Single Read
					VISIT 4	30OCT2013	16:42	N	Double Read
					VISIT 5	17DEC2013	16:32	N	Double Read
					VISIT 6	11MAR2014	16:49	N	Double Read
					VISIT 7	25SEP2014	16:20	N	Double Read
					VISIT 8	16SEP2015	15:31	N	Double Read
					VISIT 11	10OCT2018	16:18	N	Double Read
Relevant scoliosis	5_S		General		Baseline	11JUN2013	16:00	N	Double Read
					VISIT 3A	16SEP2013	13:15	N	Double Read
					VISIT 3K	19SEP2013	16:33	N	Single Read
					VISIT 3L	08OCT2013	17:08	N	Single Read
					VISIT 4	30OCT2013	16:42	N	Double Read
					VISIT 5	17DEC2013	16:32	N	Double Read
					VISIT 6	11MAR2014	16:49	N	Double Read
					VISIT 7	25SEP2014	16:20	N	Double Read
					VISIT 8	16SEP2015	15:31	N	Double Read
					VISIT 11	10OCT2018	16:18	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		VISIT 8	16SEP2015	15:31	N	Double Read
					VISIT 11	10OCT2018	16:18		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	11JUN2013	16:00	N	Double Read
					VISIT 3A	16SEP2013	13:15	N	Double Read
					VISIT 3K	19SEP2013	16:33	N	Single Read
					VISIT 3L	08OCT2013	17:08	N	Single Read
					VISIT 4	30OCT2013	16:42	N	Double Read
					VISIT 5	17DEC2013	16:32	N	Double Read
					VISIT 6	11MAR2014	16:49	N	Double Read
					VISIT 7	25SEP2014	16:20	N	Double Read
					VISIT 8	16SEP2015	15:31	N	Double Read
					VISIT 11	10OCT2018	16:18	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11JUN2013	16:00	N	Double Read
					VISIT 3A	16SEP2013	13:15	N	Double Read
					VISIT 3K	19SEP2013	16:33	N	Single Read
					VISIT 3L	08OCT2013	17:08	N	Single Read
					VISIT 4	30OCT2013	16:42	N	Double Read
					VISIT 5	17DEC2013	16:32	N	Double Read
					VISIT 6	11MAR2014	16:49	N	Double Read
					VISIT 7	25SEP2014	16:20	N	Double Read
					VISIT 8	16SEP2015	15:31	N	Double Read
					VISIT 11	10OCT2018	16:18	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 11	10OCT2018	16:18		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11JUN2013	16:00	78.296	Double Read
					VISIT 3A	16SEP2013	13:15	89.41296	Double Read
					VISIT 3K	19SEP2013	16:33	81.91488	Single Read
					VISIT 3L	08OCT2013	17:08	86.62656	Single Read
					VISIT 4	30OCT2013	16:42	85.52592	Double Read
					VISIT 5	17DEC2013	16:32	78.0392	Double Read
					VISIT 6	11MAR2014	16:49	73.48752	Double Read
					VISIT 7	25SEP2014	16:20	74.86864	Double Read
					VISIT 8	16SEP2015	15:31	89.99024	Double Read
					VISIT 11	10OCT2018	16:18	67.32192	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11JUN2013	16:00	80.19792	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 3A	16SEP2013	13:15	83.51952	Double Read
					VISIT 3K	19SEP2013	16:33	84.42848	Single Read
					VISIT 3L	08OCT2013	17:08	79.97184	Single Read
					VISIT 4	30OCT2013	16:42	82.08768	Double Read
					VISIT 5	17DEC2013	16:32	69.4672	Double Read
					VISIT 6	11MAR2014	16:49	68.8864	Double Read
					VISIT 7	25SEP2014	16:20	74.24368	Double Read
					VISIT 8	16SEP2015	15:31	79.5728	Double Read
					VISIT 11	10OCT2018	16:18	75.53104	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15	higher equal	Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15	equal equal	Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	11JUN2013	16:00	equal	Double Read
					VISIT 3A	16SEP2013	13:15	equal	Double Read
					VISIT 3K	19SEP2013	16:33	higher	Single Read
					VISIT 3L	08OCT2013	17:08	higher	Single Read
					VISIT 4	30OCT2013	16:42	equal	Double Read
					VISIT 5	17DEC2013	16:32	equal	Double Read
					VISIT 6	11MAR2014	16:49	equal	Double Read
					VISIT 7	25SEP2014	16:20	equal	Double Read
					VISIT 8	16SEP2015	15:31	equal	Double Read
					VISIT 11	10OCT2018	16:18	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33	higher	Single Read
					VISIT 3L	08OCT2013	17:08	higher	Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33	equal	Single Read
					VISIT 3L	08OCT2013	17:08	equal	Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11JUN2013	16:00	8.49501613725	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	16SEP2013	13:15	4.98273483948	Double Read
					VISIT 3K	19SEP2013	16:33	8.08076099881	Single Read
					VISIT 3L	08OCT2013	17:08	10.5316799728	Single Read
					VISIT 4	30OCT2013	16:42	8.01200611517	Double Read
					VISIT 5	17DEC2013	16:32	3.78539154069	Double Read
					VISIT 6	11MAR2014	16:49	6.79463224053	Double Read
					VISIT 7	25SEP2014	16:20	9.75128928146	Double Read
					VISIT 8	16SEP2015	15:31	8.6736334296	Double Read
					VISIT 11	10OCT2018	16:18	8.06053337863	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11JUN2013	16:00	7.60888058434	Double Read
					VISIT 3A	16SEP2013	13:15	7.28570069645	Double Read
					VISIT 3K	19SEP2013	16:33	9.49630032275	Single Read
					VISIT 3L	08OCT2013	17:08	7.71946322405	Single Read
					VISIT 4	30OCT2013	16:42	7.56585017836	Double Read
					VISIT 5	17DEC2013	16:32	9.79773738746	Double Read
					VISIT 6	11MAR2014	16:49	10.3875522337	Double Read
					VISIT 7	25SEP2014	16:20	8.45131985731	Double Read
					VISIT 8	16SEP2015	15:31	7.54770171563	Double Read
					VISIT 11	10OCT2018	16:18	8.87682690674	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
Volume (mm ³) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
Volume (mm ³) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
Volume (mm ³) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	11JUN2013	16:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
Volume (mm ³) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11JUN2013	16:00	13983.0	Double Read
					VISIT 3A	16SEP2013	13:15	14856.5	Double Read
					VISIT 3K	19SEP2013	16:33	13627	Single Read
					VISIT 3L	08OCT2013	17:08	14658	Single Read
					VISIT 4	30OCT2013	16:42	14011.0	Double Read
					VISIT 5	17DEC2013	16:32	13198.0	Double Read
					VISIT 6	11MAR2014	16:49	14127.5	Double Read
					VISIT 7	25SEP2014	16:20	13427.0	Double Read
					VISIT 8	16SEP2015	15:31	14207.0	Double Read
Volume (mm ³) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
Volume (mm ³) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0115 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read
Volume (mm ³) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11JUN2013	16:00	21914.0	Double Read
					VISIT 3A	16SEP2013	13:15	22981.5	Double Read
					VISIT 3K	19SEP2013	16:33	22907	Single Read
					VISIT 3L	08OCT2013	17:08	22137	Single Read
					VISIT 4	30OCT2013	16:42	21382.5	Double Read
					VISIT 5	17DEC2013	16:32	21273.0	Double Read
					VISIT 6	11MAR2014	16:49	22390.5	Double Read
					VISIT 7	25SEP2014	16:20	21998.5	Double Read
					VISIT 8	16SEP2015	15:31	21152.5	Double Read
					VISIT 11	10OCT2018	16:18	21080.5	Double Read
Volume (mm ³) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	11JUN2013	16:00		Double Read
					VISIT 3A	16SEP2013	13:15		Double Read
					VISIT 3K	19SEP2013	16:33		Single Read
					VISIT 3L	08OCT2013	17:08		Single Read
					VISIT 4	30OCT2013	16:42		Double Read
					VISIT 5	17DEC2013	16:32		Double Read
					VISIT 6	11MAR2014	16:49		Double Read
					VISIT 7	25SEP2014	16:20		Double Read
					VISIT 8	16SEP2015	15:31		Double Read
					VISIT 11	10OCT2018	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0116 Age=26 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUN2013	16:36		Single Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	14JUN2013	16:36	4	Single Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUN2013	16:36	4	Single Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUN2013	16:36		Single Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	14JUN2013	16:36	N	Single Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUN2013	16:36	N	Single Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUN2013	16:36		Single Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	14JUN2013	16:36	Y	Single Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUN2013	16:36	N	Single Read
Extradiscal fluid collection	5_S		General		Baseline	14JUN2013	16:36	N	Single Read
Fracture	5_S		General		Baseline	14JUN2013	16:36	N	Single Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JUN2013	16:36		Single Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JUN2013	16:36	14.19	Single Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JUN2013	16:36	15.88	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0116 Age=26 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JUN2013	16:36		Single Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JUN2013	16:36	8.16416	Single Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JUN2013	16:36	9.51887	Single Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUN2013	16:36		Single Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	14JUN2013	16:36	N	Single Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUN2013	16:36	N	Single Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUN2013	16:36		Single Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	14JUN2013	16:36	N	Single Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUN2013	16:36	N	Single Read
Normal lordotic LS	5_S		General		Baseline	14JUN2013	16:36	Y	Single Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUN2013	16:36		Single Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	14JUN2013	16:36	0	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0116 Age=26 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUN2013	16:36	0	Single Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUN2013	16:36		Single Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	14JUN2013	16:36	N	Single Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUN2013	16:36	N	Single Read
Relevant scoliosis	5_S		General		Baseline	14JUN2013	16:36	N	Single Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUN2013	16:36		Single Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	14JUN2013	16:36	N	Single Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUN2013	16:36	N	Single Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	14JUN2013	16:36		Single Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JUN2013	16:36		Single Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	14JUN2013	16:36		Single Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	14JUN2013	16:36		Single Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JUN2013	16:36	88.34272	Single Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	14JUN2013	16:36		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0116 Age=26 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JUN2013	16:36		Single Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JUN2013	16:36	76.01312	Single Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	14JUN2013	16:36		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JUN2013	16:36		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	14JUN2013	16:36		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JUN2013	16:36		Single Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JUN2013	16:36		Single Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	14JUN2013	16:36		Single Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JUN2013	16:36	higher	Single Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JUN2013	16:36		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0116 Age=26 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	14JUN2013	16:36	higher	Single Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JUN2013	16:36	lower	Single Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JUN2013	16:36		Single Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	14JUN2013	16:36		Single Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JUN2013	16:36		Single Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	14JUN2013	16:36		Single Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JUN2013	16:36		Single Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	14JUN2013	16:36		Single Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	14JUN2013	16:36		Single Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JUN2013	16:36	6.3529811449	Single Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	14JUN2013	16:36		Single Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JUN2013	16:36		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0116 Age=26 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JUN2013	16:36	6.53726516052	Single Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	14JUN2013	16:36		Single Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	14JUN2013	16:36		Single Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JUN2013	16:36		Single Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	14JUN2013	16:36		Single Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	14JUN2013	16:36		Single Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JUN2013	16:36	15371	Single Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	14JUN2013	16:36		Single Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JUN2013	16:36		Single Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JUN2013	16:36	15646	Single Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	14JUN2013	16:36		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0117 Age=48 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	18JUN2013	16:23		Single Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	18JUN2013	16:23	4	Single Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18JUN2013	16:23	4	Single Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	18JUN2013	16:23		Single Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	18JUN2013	16:23	N	Single Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18JUN2013	16:23	N	Single Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	18JUN2013	16:23		Single Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	18JUN2013	16:23	Y	Single Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18JUN2013	16:23	N	Single Read
Extradiscal fluid collection	5_S		General		Baseline	18JUN2013	16:23	N	Single Read
Fracture	5_S		General		Baseline	18JUN2013	16:23	N	Single Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18JUN2013	16:23		Single Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18JUN2013	16:23	15.85	Single Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18JUN2013	16:23	17.27	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0117 Age=48 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18JUN2013	16:23		Single Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18JUN2013	16:23	9.21696	Single Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18JUN2013	16:23	12.2879	Single Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	18JUN2013	16:23		Single Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	18JUN2013	16:23	N	Single Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18JUN2013	16:23	N	Single Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	18JUN2013	16:23		Single Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	18JUN2013	16:23	N	Single Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18JUN2013	16:23	N	Single Read
Normal lordotic LS	5_S		General		Baseline	18JUN2013	16:23	Y	Single Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	18JUN2013	16:23		Single Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	18JUN2013	16:23	0	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0117 Age=48 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18JUN2013	16:23	0	Single Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	18JUN2013	16:23		Single Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	18JUN2013	16:23	N	Single Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18JUN2013	16:23	N	Single Read
Relevant scoliosis	5_S		General		Baseline	18JUN2013	16:23	N	Single Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	18JUN2013	16:23		Single Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	18JUN2013	16:23	N	Single Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18JUN2013	16:23	N	Single Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	18JUN2013	16:23		Single Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18JUN2013	16:23		Single Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	18JUN2013	16:23		Single Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	18JUN2013	16:23		Single Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18JUN2013	16:23	99.62848	Single Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	18JUN2013	16:23		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0117 Age=48 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	18JUN2013	16:23		Single Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18JUN2013	16:23	81.0784	Single Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	18JUN2013	16:23		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	18JUN2013	16:23		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	18JUN2013	16:23		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	18JUN2013	16:23		Single Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	18JUN2013	16:23		Single Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	18JUN2013	16:23		Single Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	18JUN2013	16:23		Single Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	18JUN2013	16:23		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0117 Age=48 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	18JUN2013	16:23	equal	Single Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	18JUN2013	16:23		Single Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	18JUN2013	16:23		Single Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	18JUN2013	16:23		Single Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	18JUN2013	16:23		Single Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	18JUN2013	16:23		Single Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18JUN2013	16:23		Single Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	18JUN2013	16:23		Single Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	18JUN2013	16:23		Single Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18JUN2013	16:23	3.75323254629	Single Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	18JUN2013	16:23		Single Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	18JUN2013	16:23		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0117 Age=48 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18JUN2013	16:23	8.05649057245	Single Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	18JUN2013	16:23		Single Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	18JUN2013	16:23		Single Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18JUN2013	16:23		Single Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	18JUN2013	16:23		Single Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	18JUN2013	16:23		Single Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18JUN2013	16:23	16511	Single Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	18JUN2013	16:23		Single Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	18JUN2013	16:23		Single Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18JUN2013	16:23	22555	Single Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	18JUN2013	16:23		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	08JUL2013	16:28	3	Double Read
					VISIT 3A	07OCT2013	15:56	3	Double Read
					VISIT 3K	10OCT2013	16:29	4	Single Read
					VISIT 3L	30OCT2013	16:26	4	Single Read
					VISIT 4	20NOV2013	16:10	4	Double Read
					VISIT 5	07JAN2014	15:39	4	Double Read
					VISIT 6	25MAR2014	16:01	4	Double Read
					VISIT 7	08OCT2014	16:30	3	Double Read
					VISIT 8	07OCT2015	16:09	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	08JUL2013	16:28	3	Double Read
					VISIT 3A	07OCT2013	15:56	3	Double Read
					VISIT 3K	10OCT2013	16:29	4	Single Read
					VISIT 3L	30OCT2013	16:26	4	Single Read
					VISIT 4	20NOV2013	16:10	3	Double Read
					VISIT 5	07JAN2014	15:39	3	Double Read
					VISIT 6	25MAR2014	16:01	3	Double Read
					VISIT 7	08OCT2014	16:30	3	Double Read
					VISIT 8	07OCT2015	16:09	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	08JUL2013	16:28	N	Double Read
					VISIT 3A	07OCT2013	15:56	N	Double Read
					VISIT 3K	10OCT2013	16:29	N	Single Read
					VISIT 3L	30OCT2013	16:26	N	Single Read
					VISIT 4	20NOV2013	16:10	N	Double Read
					VISIT 5	07JAN2014	15:39	N	Double Read
					VISIT 6	25MAR2014	16:01	N	Double Read
					VISIT 7	08OCT2014	16:30	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	08JUL2013	16:28	N	Double Read
					VISIT 3A	07OCT2013	15:56	N	Double Read
					VISIT 3K	10OCT2013	16:29	N	Single Read
					VISIT 3L	30OCT2013	16:26	N	Single Read
					VISIT 4	20NOV2013	16:10	N	Double Read
					VISIT 5	07JAN2014	15:39	N	Double Read
					VISIT 6	25MAR2014	16:01	N	Double Read
					VISIT 7	08OCT2014	16:30	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 8	07OCT2015	16:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	08JUL2013	16:28	Y	Double Read
					VISIT 3A	07OCT2013	15:56	N	Double Read
					VISIT 3K	10OCT2013	16:29	Y	Single Read
					VISIT 3L	30OCT2013	16:26	Y	Single Read
					VISIT 4	20NOV2013	16:10	Y	Double Read
					VISIT 5	07JAN2014	15:39	Y	Double Read
					VISIT 6	25MAR2014	16:01	Y	Double Read
					VISIT 7	08OCT2014	16:30	Y	Double Read
					VISIT 8	07OCT2015	16:09	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	08JUL2013	16:28	N	Double Read
					VISIT 3A	07OCT2013	15:56	N	Double Read
					VISIT 3K	10OCT2013	16:29	N	Single Read
					VISIT 3L	30OCT2013	16:26	N	Single Read
					VISIT 4	20NOV2013	16:10	N	Double Read
					VISIT 5	07JAN2014	15:39	N	Double Read
					VISIT 6	25MAR2014	16:01	N	Double Read
					VISIT 7	08OCT2014	16:30	N	Double Read
					VISIT 8	07OCT2015	16:09	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	08JUL2013	16:28	N	Double Read
					VISIT 3A	07OCT2013	15:56	N	Double Read
					VISIT 3K	10OCT2013	16:29	N	Single Read
					VISIT 3L	30OCT2013	16:26	N	Single Read
					VISIT 4	20NOV2013	16:10	N	Double Read
					VISIT 5	07JAN2014	15:39	N	Double Read
					VISIT 6	25MAR2014	16:01	N	Double Read
					VISIT 7	08OCT2014	16:30	N	Double Read
					VISIT 8	07OCT2015	16:09	N	Double Read
Fracture	5_S		General		Baseline	08JUL2013	16:28	N	Double Read
					VISIT 3A	07OCT2013	15:56	N	Double Read
					VISIT 3K	10OCT2013	16:29	N	Single Read
					VISIT 3L	30OCT2013	16:26	N	Single Read
					VISIT 4	20NOV2013	16:10	N	Double Read
					VISIT 5	07JAN2014	15:39	N	Double Read
					VISIT 6	25MAR2014	16:01	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Fracture	5_S		General		VISIT 7	08OCT2014	16:30	N	Double Read
					VISIT 8	07OCT2015	16:09	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	08JUL2013	16:28	16.89	Double Read
					VISIT 3A	07OCT2013	15:56	17.62	Double Read
					VISIT 3K	10OCT2013	16:29	16.86	Single Read
					VISIT 3L	30OCT2013	16:26	15.60	Single Read
					VISIT 4	20NOV2013	16:10	16.295	Double Read
					VISIT 5	07JAN2014	15:39	16.825	Double Read
					VISIT 6	25MAR2014	16:01	16.74	Double Read
					VISIT 7	08OCT2014	16:30	17.31	Double Read
					VISIT 8	07OCT2015	16:09	16.88	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	08JUL2013	16:28	17.51	Double Read
					VISIT 3A	07OCT2013	15:56	15.93	Double Read
					VISIT 3K	10OCT2013	16:29	15.69	Single Read
					VISIT 3L	30OCT2013	16:26	16.31	Single Read
					VISIT 4	20NOV2013	16:10	15.96	Double Read
					VISIT 5	07JAN2014	15:39	16.265	Double Read
					VISIT 6	25MAR2014	16:01	16.015	Double Read
					VISIT 7	08OCT2014	16:30	15.59	Double Read
					VISIT 8	07OCT2015	16:09	15.62	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	08JUL2013	16:28		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	08JUL2013	16:28	7.08064	Double Read
					VISIT 3A	07OCT2013	15:56	6.414655	Double Read
					VISIT 3K	10OCT2013	16:29	6.62327	Single Read
					VISIT 3L	30OCT2013	16:26	6.71338	Single Read
					VISIT 4	20NOV2013	16:10	6.37137	Double Read
					VISIT 5	07JAN2014	15:39	6.5269	Double Read
					VISIT 6	25MAR2014	16:01	6.607895	Double Read
					VISIT 7	08OCT2014	16:30	6.370505	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	08JUL2013	16:28	13.05055	Double Read
					VISIT 3A	07OCT2013	15:56	12.20795	Double Read
					VISIT 3K	10OCT2013	16:29	13.3496	Single Read
					VISIT 3L	30OCT2013	16:26	12.716	Single Read
					VISIT 4	20NOV2013	16:10	12.28705	Double Read
					VISIT 5	07JAN2014	15:39	13.2273	Double Read
					VISIT 6	25MAR2014	16:01	12.2683	Double Read
					VISIT 7	08OCT2014	16:30	12.97345	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	08JUL2013	16:28	N	Double Read
					VISIT 3A	07OCT2013	15:56	N	Double Read
					VISIT 3K	10OCT2013	16:29	N	Single Read
					VISIT 3L	30OCT2013	16:26	N	Single Read
					VISIT 4	20NOV2013	16:10	N	Double Read
					VISIT 5	07JAN2014	15:39	N	Double Read
					VISIT 6	25MAR2014	16:01	N	Double Read
					VISIT 7	08OCT2014	16:30	N	Double Read
					VISIT 8	07OCT2015	16:09	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	08JUL2013	16:28	N	Double Read
					VISIT 3A	07OCT2013	15:56	N	Double Read
					VISIT 3K	10OCT2013	16:29	N	Single Read
					VISIT 3L	30OCT2013	16:26	N	Single Read
					VISIT 4	20NOV2013	16:10	N	Double Read
					VISIT 5	07JAN2014	15:39	N	Double Read
					VISIT 6	25MAR2014	16:01	N	Double Read
					VISIT 7	08OCT2014	16:30	N	Double Read
					VISIT 8	07OCT2015	16:09	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	08JUL2013	16:28	N	Double Read
					VISIT 3A	07OCT2013	15:56	N	Double Read
					VISIT 3K	10OCT2013	16:29	N	Single Read
					VISIT 3L	30OCT2013	16:26	N	Single Read
					VISIT 4	20NOV2013	16:10	N	Double Read
					VISIT 5	07JAN2014	15:39	N	Double Read
					VISIT 6	25MAR2014	16:01	N	Double Read
					VISIT 7	08OCT2014	16:30	N	Double Read
					VISIT 8	07OCT2015	16:09	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	08JUL2013	16:28	N	Double Read
					VISIT 3A	07OCT2013	15:56	N	Double Read
					VISIT 3K	10OCT2013	16:29	N	Single Read
					VISIT 3L	30OCT2013	16:26	N	Single Read
					VISIT 4	20NOV2013	16:10	N	Double Read
					VISIT 5	07JAN2014	15:39	N	Double Read
					VISIT 6	25MAR2014	16:01	N	Double Read
					VISIT 7	08OCT2014	16:30	N	Double Read
					VISIT 8	07OCT2015	16:09	N	Double Read
Normal lordotic LS	5_S		General		Baseline	08JUL2013	16:28	Y	Double Read
					VISIT 3A	07OCT2013	15:56	Y	Double Read
					VISIT 3K	10OCT2013	16:29	Y	Single Read
					VISIT 3L	30OCT2013	16:26	Y	Single Read
					VISIT 4	20NOV2013	16:10	Y	Double Read
					VISIT 5	07JAN2014	15:39	Y	Double Read
					VISIT 6	25MAR2014	16:01	Y	Double Read
					VISIT 7	08OCT2014	16:30	Y	Double Read
					VISIT 8	07OCT2015	16:09	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	08JUL2013	16:28	2	Double Read
					VISIT 3A	07OCT2013	15:56	2	Double Read
					VISIT 3K	10OCT2013	16:29	2	Single Read
					VISIT 3L	30OCT2013	16:26	2	Single Read
					VISIT 4	20NOV2013	16:10	2	Double Read
					VISIT 5	07JAN2014	15:39	2	Double Read
					VISIT 6	25MAR2014	16:01	2	Double Read
					VISIT 7	08OCT2014	16:30	2	Double Read
					VISIT 8	07OCT2015	16:09	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	08JUL2013	16:28	0	Double Read
					VISIT 3A	07OCT2013	15:56	0	Double Read
					VISIT 3K	10OCT2013	16:29	0	Single Read
					VISIT 3L	30OCT2013	16:26	0	Single Read
					VISIT 4	20NOV2013	16:10	0	Double Read
					VISIT 5	07JAN2014	15:39	0	Double Read
					VISIT 6	25MAR2014	16:01	0	Double Read
					VISIT 7	08OCT2014	16:30	0	Double Read
					VISIT 8	07OCT2015	16:09	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56	N	Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	08JUL2013	16:28	N	Double Read
					VISIT 3A	07OCT2013	15:56	N	Double Read
					VISIT 3K	10OCT2013	16:29	N	Single Read
					VISIT 3L	30OCT2013	16:26	N	Single Read
					VISIT 4	20NOV2013	16:10	N	Double Read
					VISIT 5	07JAN2014	15:39	N	Double Read
					VISIT 6	25MAR2014	16:01	N	Double Read
					VISIT 7	08OCT2014	16:30	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	08JUL2013	16:28	N	Double Read
					VISIT 3A	07OCT2013	15:56	N	Double Read
					VISIT 3K	10OCT2013	16:29	N	Single Read
					VISIT 3L	30OCT2013	16:26	N	Single Read
					VISIT 4	20NOV2013	16:10	N	Double Read
					VISIT 5	07JAN2014	15:39	N	Double Read
					VISIT 6	25MAR2014	16:01	N	Double Read
					VISIT 7	08OCT2014	16:30	N	Double Read
Relevant scoliosis	5_S		General		Baseline	08JUL2013	16:28	N	Double Read
					VISIT 3A	07OCT2013	15:56	N	Double Read
					VISIT 3K	10OCT2013	16:29	N	Single Read
					VISIT 3L	30OCT2013	16:26	N	Single Read
					VISIT 4	20NOV2013	16:10	N	Double Read
					VISIT 5	07JAN2014	15:39	N	Double Read
					VISIT 6	25MAR2014	16:01	N	Double Read
					VISIT 7	08OCT2014	16:30	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56	N	Double Read
					VISIT 3K	10OCT2013	16:29	N	Single Read
					VISIT 3L	30OCT2013	16:26	N	Single Read
					VISIT 4	20NOV2013	16:10	N	Double Read
					VISIT 5	07JAN2014	15:39	N	Double Read
					VISIT 6	25MAR2014	16:01	N	Double Read
					VISIT 7	08OCT2014	16:30	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	08JUL2013	16:28	N	Double Read
					VISIT 3A	07OCT2013	15:56	N	Double Read
					VISIT 3K	10OCT2013	16:29	N	Single Read
					VISIT 3L	30OCT2013	16:26	N	Single Read
					VISIT 4	20NOV2013	16:10	N	Double Read
					VISIT 5	07JAN2014	15:39	N	Double Read
					VISIT 6	25MAR2014	16:01	N	Double Read
					VISIT 7	08OCT2014	16:30	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	08JUL2013	16:28	N	Double Read
					VISIT 3A	07OCT2013	15:56	N	Double Read
					VISIT 3K	10OCT2013	16:29	N	Single Read
					VISIT 3L	30OCT2013	16:26	N	Single Read
					VISIT 4	20NOV2013	16:10	N	Double Read
					VISIT 5	07JAN2014	15:39	N	Double Read
					VISIT 6	25MAR2014	16:01	N	Double Read
					VISIT 7	08OCT2014	16:30	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	08JUL2013	16:28	93.97072	Double Read
					VISIT 3A	07OCT2013	15:56	93.24496	Double Read
					VISIT 3K	10OCT2013	16:29	96.87968	Single Read
					VISIT 3L	30OCT2013	16:26	87.54208	Single Read
					VISIT 4	20NOV2013	16:10	103.97344	Double Read
					VISIT 5	07JAN2014	15:39	74.45424	Double Read
					VISIT 6	25MAR2014	16:01	79.41824	Double Read
					VISIT 7	08OCT2014	16:30	81.42224	Double Read
					VISIT 8	07OCT2015	16:09	81.48464	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	08JUL2013	16:28	85.53136	Double Read
					VISIT 3A	07OCT2013	15:56	90.79488	Double Read
					VISIT 3K	10OCT2013	16:29	88.38592	Single Read
					VISIT 3L	30OCT2013	16:26	82.57056	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 4	20NOV2013	16:10	85.89024	Double Read
					VISIT 5	07JAN2014	15:39	65.82432	Double Read
					VISIT 6	25MAR2014	16:01	70.80624	Double Read
					VISIT 7	08OCT2014	16:30	72.3904	Double Read
					VISIT 8	07OCT2015	16:09	73.044	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29	higher	Single Read
					VISIT 3L	30OCT2013	16:26	higher	Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29	equal	Single Read
					VISIT 3L	30OCT2013	16:26	equal	Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39	lower	Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	08JUL2013	16:28	higher	Double Read
					VISIT 3A	07OCT2013	15:56	higher	Double Read
					VISIT 3K	10OCT2013	16:29	higher	Single Read
					VISIT 3L	30OCT2013	16:26	higher	Single Read
					VISIT 4	20NOV2013	16:10	higher	Double Read
					VISIT 5	07JAN2014	15:39	higher	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		VISIT 6	25MAR2014	16:01	higher	Double Read
					VISIT 7	08OCT2014	16:30	higher	Double Read
					VISIT 8	07OCT2015	16:09	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39	lower	Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29	higher	Single Read
					VISIT 3L	30OCT2013	16:26	higher	Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 8	07OCT2015	16:09		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56	equal equal	Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	08JUL2013	16:28	10.596392050	Double Read
					VISIT 3A	07OCT2013	15:56	4.8088941736	Double Read
					VISIT 3K	10OCT2013	16:29	7.6593986750	Single Read
					VISIT 3L	30OCT2013	16:26	9.3034143027	Single Read
					VISIT 4	20NOV2013	16:10	8.5996738576	Double Read
					VISIT 5	07JAN2014	15:39	8.6284083574	Double Read
					VISIT 6	25MAR2014	16:01	7.0858297944	Double Read
					VISIT 7	08OCT2014	16:30	13.580771190	Double Read
								2 1 5 3 2 6 7	

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	07OCT2015	16:09	9.13775437405	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	08JUL2013	16:28	8.11541362324	Double Read
					VISIT 3A	07OCT2013	15:56	8.63484966876	Double Read
					VISIT 3K	10OCT2013	16:29	8.9179548157	Single Read
					VISIT 3L	30OCT2013	16:26	9.11177849499	Single Read
					VISIT 4	20NOV2013	16:10	9.36134533717	Double Read
					VISIT 5	07JAN2014	15:39	6.6253100051	Double Read
					VISIT 6	25MAR2014	16:01	7.62899269577	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 7	08OCT2014	16:30	9.36101919484	Double Read
					VISIT 8	07OCT2015	16:09	10.0220825548	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	08JUL2013	16:28	14309.0	Double Read
					VISIT 3A	07OCT2013	15:56	19008.5	Double Read
					VISIT 3K	10OCT2013	16:29	17026	Single Read
					VISIT 3L	30OCT2013	16:26	17846	Single Read
					VISIT 4	20NOV2013	16:10	17794.5	Double Read
					VISIT 5	07JAN2014	15:39	18779.5	Double Read
					VISIT 6	25MAR2014	16:01	18247.0	Double Read
					VISIT 7	08OCT2014	16:30	17172.5	Double Read
					VISIT 8	07OCT2015	16:09	17751.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
					VISIT 8	07OCT2015	16:09		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	08JUL2013	16:28	21635.0	Double Read
					VISIT 3A	07OCT2013	15:56	24825.0	Double Read
					VISIT 3K	10OCT2013	16:29	24254	Single Read
					VISIT 3L	30OCT2013	16:26	25393	Single Read
					VISIT 4	20NOV2013	16:10	24966.5	Double Read
					VISIT 5	07JAN2014	15:39	23846.5	Double Read
					VISIT 6	25MAR2014	16:01	24952.5	Double Read
					VISIT 7	08OCT2014	16:30	24779.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	08JUL2013	16:28		Double Read
					VISIT 3A	07OCT2013	15:56		Double Read
					VISIT 3K	10OCT2013	16:29		Single Read
					VISIT 3L	30OCT2013	16:26		Single Read
					VISIT 4	20NOV2013	16:10		Double Read
					VISIT 5	07JAN2014	15:39		Double Read
					VISIT 6	25MAR2014	16:01		Double Read
					VISIT 7	08OCT2014	16:30		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0118 Age=47 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	07OCT2015	16:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	22JUL2013	16:01	3	Double Read
					VISIT 3A	14OCT2013	16:18	3	Double Read
					VISIT 3K	17OCT2013	16:40	3	Single Read
					VISIT 3L	06NOV2013	16:18	3	Single Read
					VISIT 4	19NOV2013	15:53	3	Double Read
					VISIT 5	14JAN2014	16:07	3	Double Read
					VISIT 6	03APR2014	16:30	4	Double Read
					VISIT 7	15OCT2014	16:05	4	Double Read
					VISIT 8	14OCT2015	16:34	4	Double Read
					VISIT 11	10OCT2018	17:03	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22JUL2013	16:01	3	Double Read
					VISIT 3A	14OCT2013	16:18	2	Double Read
					VISIT 3K	17OCT2013	16:40	3	Single Read
					VISIT 3L	06NOV2013	16:18	3	Single Read
					VISIT 4	19NOV2013	15:53	2	Double Read
					VISIT 5	14JAN2014	16:07	2	Double Read
					VISIT 6	03APR2014	16:30	2	Double Read
					VISIT 7	15OCT2014	16:05	3	Double Read
					VISIT 8	14OCT2015	16:34	3	Double Read
					VISIT 11	10OCT2018	17:03	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	22JUL2013	16:01		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	22JUL2013	16:01	N	Double Read
					VISIT 3A	14OCT2013	16:18	N	Double Read
					VISIT 3K	17OCT2013	16:40	N	Single Read
					VISIT 3L	06NOV2013	16:18	N	Single Read
					VISIT 4	19NOV2013	15:53	N	Double Read
					VISIT 5	14JAN2014	16:07	N	Double Read
					VISIT 6	03APR2014	16:30	N	Double Read
					VISIT 7	15OCT2014	16:05	N	Double Read
					VISIT 8	14OCT2015	16:34	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22JUL2013	16:01	N	Double Read
					VISIT 3A	14OCT2013	16:18	N	Double Read
					VISIT 3K	17OCT2013	16:40	N	Single Read
					VISIT 3L	06NOV2013	16:18	N	Single Read
					VISIT 4	19NOV2013	15:53	N	Double Read
					VISIT 5	14JAN2014	16:07	N	Double Read
					VISIT 6	03APR2014	16:30	N	Double Read
					VISIT 7	15OCT2014	16:05	N	Double Read
					VISIT 8	14OCT2015	16:34	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	22JUL2013	16:01	Y	Double Read
					VISIT 3A	14OCT2013	16:18	Y	Double Read
					VISIT 3K	17OCT2013	16:40	Y	Single Read
					VISIT 3L	06NOV2013	16:18	Y	Single Read
					VISIT 4	19NOV2013	15:53	Y	Double Read
					VISIT 5	14JAN2014	16:07	Y	Double Read
					VISIT 6	03APR2014	16:30	Y	Double Read
					VISIT 7	15OCT2014	16:05	Y	Double Read
					VISIT 8	14OCT2015	16:34	Y	Double Read
					VISIT 11	10OCT2018	17:03	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22JUL2013	16:01	N	Double Read
					VISIT 3A	14OCT2013	16:18	N	Double Read
					VISIT 3K	17OCT2013	16:40	N	Single Read
					VISIT 3L	06NOV2013	16:18	N	Single Read
					VISIT 4	19NOV2013	15:53	N	Double Read
					VISIT 5	14JAN2014	16:07	N	Double Read
					VISIT 6	03APR2014	16:30	N	Double Read
					VISIT 7	15OCT2014	16:05	N	Double Read
					VISIT 8	14OCT2015	16:34	N	Double Read
					VISIT 11	10OCT2018	17:03	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	22JUL2013	16:01	N	Double Read
					VISIT 3A	14OCT2013	16:18	N	Double Read
					VISIT 3K	17OCT2013	16:40	Y	Single Read
					VISIT 3L	06NOV2013	16:18	N	Single Read
					VISIT 4	19NOV2013	15:53	N	Double Read
					VISIT 5	14JAN2014	16:07	N	Double Read
					VISIT 6	03APR2014	16:30	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 7	15OCT2014	16:05	N	Double Read
					VISIT 8	14OCT2015	16:34	N	Double Read
					VISIT 11	10OCT2018	17:03	N	Double Read
Fracture	5_S		General		Baseline	22JUL2013	16:01	N	Double Read
					VISIT 3A	14OCT2013	16:18	N	Double Read
					VISIT 3K	17OCT2013	16:40	N	Single Read
					VISIT 3L	06NOV2013	16:18	N	Single Read
					VISIT 4	19NOV2013	15:53	N	Double Read
					VISIT 5	14JAN2014	16:07	N	Double Read
					VISIT 6	03APR2014	16:30	N	Double Read
					VISIT 7	15OCT2014	16:05	N	Double Read
					VISIT 8	14OCT2015	16:34	N	Double Read
					VISIT 11	10OCT2018	17:03	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22JUL2013	16:01	22.365	Double Read
					VISIT 3A	14OCT2013	16:18	22.115	Double Read
					VISIT 3K	17OCT2013	16:40	19.77	Single Read
					VISIT 3L	06NOV2013	16:18	20.67	Single Read
					VISIT 4	19NOV2013	15:53	20.55	Double Read
					VISIT 5	14JAN2014	16:07	20.42	Double Read
					VISIT 6	03APR2014	16:30	20.895	Double Read
					VISIT 7	15OCT2014	16:05	21.29	Double Read
					VISIT 8	14OCT2015	16:34	19.99	Double Read
					VISIT 11	10OCT2018	17:03	20.7	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22JUL2013	16:01	18.595	Double Read
					VISIT 3A	14OCT2013	16:18	18.35	Double Read
					VISIT 3K	17OCT2013	16:40	17.10	Single Read
					VISIT 3L	06NOV2013	16:18	16.40	Single Read
					VISIT 4	19NOV2013	15:53	17.365	Double Read
					VISIT 5	14JAN2014	16:07	15.1	Double Read
					VISIT 6	03APR2014	16:30	17.335	Double Read
					VISIT 7	15OCT2014	16:05	17.31	Double Read
					VISIT 8	14OCT2015	16:34	15.47	Double Read
					VISIT 11	10OCT2018	17:03	16.7	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22JUL2013	16:01	8.802335	Double Read
					VISIT 3A	14OCT2013	16:18	9.51344	Double Read
					VISIT 3K	17OCT2013	16:40	9.38544	Single Read
					VISIT 3L	06NOV2013	16:18	9.10281	Single Read
					VISIT 4	19NOV2013	15:53	8.45128	Double Read
					VISIT 5	14JAN2014	16:07	8.76583	Double Read
					VISIT 6	03APR2014	16:30	7.626745	Double Read
					VISIT 7	15OCT2014	16:05	7.88128	Double Read
					VISIT 8	14OCT2015	16:34	7.400045	Double Read
					VISIT 11	10OCT2018	17:03	7.426425	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22JUL2013	16:01	10.9851	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 3A	14OCT2013	16:18	10.43865	Double Read
					VISIT 3K	17OCT2013	16:40	10.7565	Single Read
					VISIT 3L	06NOV2013	16:18	11.0479	Single Read
					VISIT 4	19NOV2013	15:53	10.06201	Double Read
					VISIT 5	14JAN2014	16:07	10.49911	Double Read
					VISIT 6	03APR2014	16:30	9.96683	Double Read
					VISIT 7	15OCT2014	16:05	10.111285	Double Read
					VISIT 8	14OCT2015	16:34	9.505055	Double Read
					VISIT 11	10OCT2018	17:03	10.18081	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	22JUL2013	16:01	N	Double Read
					VISIT 3A	14OCT2013	16:18	N	Double Read
					VISIT 3K	17OCT2013	16:40	N	Single Read
					VISIT 3L	06NOV2013	16:18	N	Single Read
					VISIT 4	19NOV2013	15:53	N	Double Read
					VISIT 5	14JAN2014	16:07	N	Double Read
					VISIT 6	03APR2014	16:30	N	Double Read
					VISIT 7	15OCT2014	16:05	N	Double Read
					VISIT 8	14OCT2015	16:34	N	Double Read
					VISIT 11	10OCT2018	17:03	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22JUL2013	16:01	N	Double Read
					VISIT 3A	14OCT2013	16:18	N	Double Read
					VISIT 3K	17OCT2013	16:40	N	Single Read
					VISIT 3L	06NOV2013	16:18	N	Single Read
					VISIT 4	19NOV2013	15:53	N	Double Read
					VISIT 5	14JAN2014	16:07	N	Double Read
					VISIT 6	03APR2014	16:30	N	Double Read
					VISIT 7	15OCT2014	16:05	N	Double Read
					VISIT 8	14OCT2015	16:34	N	Double Read
					VISIT 11	10OCT2018	17:03	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	22JUL2013	16:01	N	Double Read
					VISIT 3A	14OCT2013	16:18	N	Double Read
					VISIT 3K	17OCT2013	16:40	N	Single Read
					VISIT 3L	06NOV2013	16:18	N	Single Read
					VISIT 4	19NOV2013	15:53	N	Double Read
					VISIT 5	14JAN2014	16:07	N	Double Read
					VISIT 6	03APR2014	16:30	N	Double Read
					VISIT 7	15OCT2014	16:05	N	Double Read
					VISIT 8	14OCT2015	16:34	N	Double Read
					VISIT 11	10OCT2018	17:03	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22JUL2013	16:01	N	Double Read
					VISIT 3A	14OCT2013	16:18	N	Double Read
					VISIT 3K	17OCT2013	16:40	N	Single Read
					VISIT 3L	06NOV2013	16:18	N	Single Read
					VISIT 4	19NOV2013	15:53	N	Double Read
					VISIT 5	14JAN2014	16:07	N	Double Read
					VISIT 6	03APR2014	16:30	N	Double Read
					VISIT 7	15OCT2014	16:05	N	Double Read
					VISIT 8	14OCT2015	16:34	N	Double Read
					VISIT 11	10OCT2018	17:03	N	Double Read
Normal lordotic LS	5_S		General		Baseline	22JUL2013	16:01	Y	Double Read
					VISIT 3A	14OCT2013	16:18	Y	Double Read
					VISIT 3K	17OCT2013	16:40	Y	Single Read
					VISIT 3L	06NOV2013	16:18	Y	Single Read
					VISIT 4	19NOV2013	15:53	Y	Double Read
					VISIT 5	14JAN2014	16:07	Y	Double Read
					VISIT 6	03APR2014	16:30	Y	Double Read
					VISIT 7	15OCT2014	16:05	Y	Double Read
					VISIT 8	14OCT2015	16:34	Y	Double Read
					VISIT 11	10OCT2018	17:03	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	22JUL2013	16:01	0	Double Read
					VISIT 3A	14OCT2013	16:18	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 3K	17OCT2013	16:40	0	Single Read
					VISIT 3L	06NOV2013	16:18	0	Single Read
					VISIT 4	19NOV2013	15:53	0	Double Read
					VISIT 5	14JAN2014	16:07	0	Double Read
					VISIT 6	03APR2014	16:30	1	Double Read
					VISIT 7	15OCT2014	16:05	0	Double Read
					VISIT 8	14OCT2015	16:34	0	Double Read
					VISIT 11	10OCT2018	17:03	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22JUL2013	16:01	0	Double Read
					VISIT 3A	14OCT2013	16:18	0	Double Read
					VISIT 3K	17OCT2013	16:40	0	Single Read
					VISIT 3L	06NOV2013	16:18	0	Single Read
					VISIT 4	19NOV2013	15:53	0	Double Read
					VISIT 5	14JAN2014	16:07	0	Double Read
					VISIT 6	03APR2014	16:30	0	Double Read
					VISIT 7	15OCT2014	16:05	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 8	14OCT2015	16:34	0	Double Read
					VISIT 11	10OCT2018	17:03	0	Double Read
					Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
					Baseline	22JUL2013	16:01	N	Double Read
					VISIT 3A	14OCT2013	16:18	N	Double Read
					VISIT 3K	17OCT2013	16:40	N	Single Read
					VISIT 3L	06NOV2013	16:18	N	Single Read
					VISIT 4	19NOV2013	15:53	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 5	14JAN2014	16:07	N	Double Read
					VISIT 6	03APR2014	16:30	N	Double Read
					VISIT 7	15OCT2014	16:05	N	Double Read
					VISIT 8	14OCT2015	16:34	N	Double Read
					VISIT 11	10OCT2018	17:03	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22JUL2013	16:01	N	Double Read
					VISIT 3A	14OCT2013	16:18	N	Double Read
					VISIT 3K	17OCT2013	16:40	N	Single Read
					VISIT 3L	06NOV2013	16:18	N	Single Read
					VISIT 4	19NOV2013	15:53	N	Double Read
					VISIT 5	14JAN2014	16:07	N	Double Read
					VISIT 6	03APR2014	16:30	N	Double Read
					VISIT 7	15OCT2014	16:05	N	Double Read
					VISIT 8	14OCT2015	16:34	N	Double Read
Relevant scoliosis	5_S		General		VISIT 11	10OCT2018	17:03	N	Double Read
					Baseline	22JUL2013	16:01	N	Double Read
					VISIT 3A	14OCT2013	16:18	N	Double Read
					VISIT 3K	17OCT2013	16:40	N	Single Read
					VISIT 3L	06NOV2013	16:18	N	Single Read
					VISIT 4	19NOV2013	15:53	N	Double Read
					VISIT 5	14JAN2014	16:07	N	Double Read
					VISIT 6	03APR2014	16:30	N	Double Read
					VISIT 7	15OCT2014	16:05	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		VISIT 8	14OCT2015	16:34	N	Double Read
					VISIT 11	10OCT2018	17:03	N	Double Read
					Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	22JUL2013	16:01	N	Double Read
					VISIT 3A	14OCT2013	16:18	N	Double Read
					VISIT 3K	17OCT2013	16:40	N	Single Read
					VISIT 3L	06NOV2013	16:18	N	Single Read
					VISIT 4	19NOV2013	15:53	N	Double Read
					VISIT 5	14JAN2014	16:07	N	Double Read
					VISIT 6	03APR2014	16:30	N	Double Read
					VISIT 7	15OCT2014	16:05	N	Double Read
					VISIT 8	14OCT2015	16:34	N	Double Read
					VISIT 11	10OCT2018	17:03	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22JUL2013	16:01	N	Double Read
					VISIT 3A	14OCT2013	16:18	N	Double Read
					VISIT 3K	17OCT2013	16:40	N	Single Read
					VISIT 3L	06NOV2013	16:18	N	Single Read
					VISIT 4	19NOV2013	15:53	N	Double Read
					VISIT 5	14JAN2014	16:07	N	Double Read
					VISIT 6	03APR2014	16:30	N	Double Read
					VISIT 7	15OCT2014	16:05	N	Double Read
					VISIT 8	14OCT2015	16:34	N	Double Read
					VISIT 11	10OCT2018	17:03	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 11	10OCT2018	17:03		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40	107.30816	Single Read
					VISIT 3L	06NOV2013	16:18	113.34432	Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22JUL2013	16:01	82.45504	Double Read
					VISIT 3A	14OCT2013	16:18	76.564	Double Read
					VISIT 3K	17OCT2013	16:40	76.09408	Single Read
					VISIT 3L	06NOV2013	16:18	77.15072	Single Read
					VISIT 4	19NOV2013	15:53	73.71584	Double Read
					VISIT 5	14JAN2014	16:07	69.52672	Double Read
					VISIT 6	03APR2014	16:30	66.05392	Double Read
					VISIT 7	15OCT2014	16:05	77.49456	Double Read
					VISIT 8	14OCT2015	16:34	73.83152	Double Read
					VISIT 11	10OCT2018	17:03	60.8408	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40	72.99168	Single Read
					VISIT 3L	06NOV2013	16:18	75.70752	Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40	87.34208	Single Read
					VISIT 3L	06NOV2013	16:18	113.33472	Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22JUL2013	16:01	90.81712	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 3A	14OCT2013	16:18	94.38736	Double Read
					VISIT 3K	17OCT2013	16:40	88.82624	Single Read
					VISIT 3L	06NOV2013	16:18	85.47168	Single Read
					VISIT 4	19NOV2013	15:53	83.956	Double Read
					VISIT 5	14JAN2014	16:07	77.03712	Double Read
					VISIT 6	03APR2014	16:30	77.73984	Double Read
					VISIT 7	15OCT2014	16:05	83.20048	Double Read
					VISIT 8	14OCT2015	16:34	79.62976	Double Read
					VISIT 11	10OCT2018	17:03	71.78368	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40	90.11296	Single Read
					VISIT 3L	06NOV2013	16:18	82.44992	Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18	equal higher	Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18	equal equal	Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	22JUL2013	16:01	lower	Double Read
					VISIT 3A	14OCT2013	16:18	lower	Double Read
					VISIT 3K	17OCT2013	16:40	lower	Single Read
					VISIT 3L	06NOV2013	16:18	lower	Single Read
					VISIT 4	19NOV2013	15:53	lower	Double Read
					VISIT 5	14JAN2014	16:07	lower	Double Read
					VISIT 6	03APR2014	16:30	lower	Double Read
					VISIT 7	15OCT2014	16:05	lower	Double Read
					VISIT 8	14OCT2015	16:34	lower	Double Read
					VISIT 11	10OCT2018	17:03	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40	equal	Single Read
					VISIT 3L	06NOV2013	16:18	higher	Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40	equal	Single Read
					VISIT 3L	06NOV2013	16:18	equal	Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40	34.2869373195	Single Read
					VISIT 3L	06NOV2013	16:18	46.555732971	Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22JUL2013	16:01	9.07179208427	Double Read
					VISIT 3A	14OCT2013	16:18	8.33050450144	Double Read
					VISIT 3K	17OCT2013	16:40	7.09877356888	Single Read
					VISIT 3L	06NOV2013	16:18	6.62434516732	Single Read
					VISIT 4	19NOV2013	15:53	7.82656701206	Double Read
					VISIT 5	14JAN2014	16:07	7.79589604213	Double Read
					VISIT 6	03APR2014	16:30	9.6912926788	Double Read
					VISIT 7	15OCT2014	16:05	9.80773229149	Double Read
					VISIT 8	14OCT2015	16:34	9.81406488874	Double Read
					VISIT 11	10OCT2018	17:03	6.97582469848	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40	8.69146254459	Single Read
					VISIT 3L	06NOV2013	16:18	4.09619840326	Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40	2.5819602514	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	VISIT 3L	06NOV2013	16:18	46.5671479531	Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22JUL2013	16:01	7.9622965857	Double Read
					VISIT 3A	14OCT2013	16:18	15.0076439613	Double Read
					VISIT 3K	17OCT2013	16:40	18.0676065908	Single Read
					VISIT 3L	06NOV2013	16:18	12.9421572957	Single Read
					VISIT 4	19NOV2013	15:53	12.0035128249	Double Read
					VISIT 5	14JAN2014	16:07	10.1779310345	Double Read
					VISIT 6	03APR2014	16:30	8.7533820282	Double Read
					VISIT 7	15OCT2014	16:05	15.8258535757	Double Read
					VISIT 8	14OCT2015	16:34	7.9142041787	Double Read
					VISIT 11	10OCT2018	17:03	10.3923220656	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40	8.33474435196	Single Read
					VISIT 3L	06NOV2013	16:18	4.24664515033	Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40		Single Read
					VISIT 3L	06NOV2013	16:18		Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40	9619	Single Read
					VISIT 3L	06NOV2013	16:18	13133	Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22JUL2013	16:01	20921.5	Double Read
					VISIT 3A	14OCT2013	16:18	20781.0	Double Read
					VISIT 3K	17OCT2013	16:40	14312	Single Read
					VISIT 3L	06NOV2013	16:18	18355	Single Read
					VISIT 4	19NOV2013	15:53	19861.0	Double Read
					VISIT 5	14JAN2014	16:07	19313.0	Double Read
					VISIT 6	03APR2014	16:30	19345.5	Double Read
					VISIT 7	15OCT2014	16:05	18589.0	Double Read
					VISIT 8	14OCT2015	16:34	17576.0	Double Read
					VISIT 11	10OCT2018	17:03	16767.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40	4693	Single Read
					VISIT 3L	06NOV2013	16:18	5222	Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0119 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	VISIT 11	10OCT2018	17:03		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40	14733	Single Read
					VISIT 3L	06NOV2013	16:18	13964	Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22JUL2013	16:01	24029.0	Double Read
					VISIT 3A	14OCT2013	16:18	24644.5	Double Read
					VISIT 3K	17OCT2013	16:40	22145	Single Read
					VISIT 3L	06NOV2013	16:18	22136	Single Read
					VISIT 4	19NOV2013	15:53	23378.5	Double Read
					VISIT 5	14JAN2014	16:07	21931.5	Double Read
					VISIT 6	03APR2014	16:30	22671.5	Double Read
					VISIT 7	15OCT2014	16:05	22012.5	Double Read
					VISIT 8	14OCT2015	16:34	21446.0	Double Read
					VISIT 11	10OCT2018	17:03	21481.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	22JUL2013	16:01		Double Read
					VISIT 3A	14OCT2013	16:18		Double Read
					VISIT 3K	17OCT2013	16:40	7412	Single Read
					VISIT 3L	06NOV2013	16:18	8172	Single Read
					VISIT 4	19NOV2013	15:53		Double Read
					VISIT 5	14JAN2014	16:07		Double Read
					VISIT 6	03APR2014	16:30		Double Read
					VISIT 7	15OCT2014	16:05		Double Read
					VISIT 8	14OCT2015	16:34		Double Read
					VISIT 11	10OCT2018	17:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0120 Age=35 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	29JUL2013	16:30		Single Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	29JUL2013	16:30	4	Single Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	29JUL2013	16:30	4	Single Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	29JUL2013	16:30		Single Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	29JUL2013	16:30	N	Single Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	29JUL2013	16:30	N	Single Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	29JUL2013	16:30		Single Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	29JUL2013	16:30	Y	Single Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	29JUL2013	16:30	N	Single Read
Extradiscal fluid collection	5_S		General		Baseline	29JUL2013	16:30	N	Single Read
Fracture	5_S		General		Baseline	29JUL2013	16:30	N	Single Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	29JUL2013	16:30		Single Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	29JUL2013	16:30	10.68	Single Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	29JUL2013	16:30	11.14	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0120 Age=35 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	29JUL2013	16:30		Single Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	29JUL2013	16:30	9.00371	Single Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	29JUL2013	16:30	10.5102	Single Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	29JUL2013	16:30		Single Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	29JUL2013	16:30	N	Single Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	29JUL2013	16:30	N	Single Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	29JUL2013	16:30		Single Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	29JUL2013	16:30	N	Single Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	29JUL2013	16:30	N	Single Read
Normal lordotic LS	5_S		General		Baseline	29JUL2013	16:30	Y	Single Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	29JUL2013	16:30		Single Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	29JUL2013	16:30	1	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0120 Age=35 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	29JUL2013	16:30	0	Single Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	29JUL2013	16:30		Single Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	29JUL2013	16:30	N	Single Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	29JUL2013	16:30	N	Single Read
Relevant scoliosis	5_S		General		Baseline	29JUL2013	16:30	N	Single Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	29JUL2013	16:30		Single Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	29JUL2013	16:30	N	Single Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	29JUL2013	16:30	N	Single Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	29JUL2013	16:30		Single Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	29JUL2013	16:30		Single Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	29JUL2013	16:30		Single Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	29JUL2013	16:30		Single Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	29JUL2013	16:30	69.61792	Single Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	29JUL2013	16:30		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0120 Age=35 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	29JUL2013	16:30		Single Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	29JUL2013	16:30	70.72352	Single Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	29JUL2013	16:30		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	29JUL2013	16:30		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	29JUL2013	16:30		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	29JUL2013	16:30		Single Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	29JUL2013	16:30		Single Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	29JUL2013	16:30		Single Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	29JUL2013	16:30		Single Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	29JUL2013	16:30		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0120 Age=35 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	29JUL2013	16:30	equal	Single Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	29JUL2013	16:30		Single Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	29JUL2013	16:30		Single Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	29JUL2013	16:30		Single Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	29JUL2013	16:30		Single Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	29JUL2013	16:30		Single Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	29JUL2013	16:30		Single Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	29JUL2013	16:30		Single Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	29JUL2013	16:30		Single Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	29JUL2013	16:30	3.7925598777	Single Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	29JUL2013	16:30		Single Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	29JUL2013	16:30		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0120 Age=35 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	29JUL2013	16:30	6.2040156276 5	Single Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	29JUL2013	16:30		Single Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	29JUL2013	16:30		Single Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	29JUL2013	16:30		Single Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	29JUL2013	16:30		Single Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	29JUL2013	16:30		Single Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	29JUL2013	16:30	9981	Single Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	29JUL2013	16:30		Single Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	29JUL2013	16:30		Single Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	29JUL2013	16:30	9697	Single Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	29JUL2013	16:30		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49	2	Double Read
					VISIT 6	14JUL2014	16:13	2	Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	18SEP2013	15:42	3	Double Read
					VISIT 3A	13JAN2014	16:15	3	Double Read
					VISIT 3K	16JAN2014	17:29	4	Single Read
					VISIT 3L	05FEB2014	16:43	4	Single Read
					VISIT 4	18FEB2014	15:52	3	Double Read
					VISIT 5	08APR2014	15:49	3	Double Read
					VISIT 6	14JUL2014	16:13	3	Double Read
					VISIT 7	28JAN2015	16:26	3	Double Read
					VISIT 8	14JAN2016	16:59	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18SEP2013	15:42	2	Double Read
					VISIT 3A	13JAN2014	16:15	2	Double Read
					VISIT 3K	16JAN2014	17:29	1	Single Read
					VISIT 3L	05FEB2014	16:43	1	Single Read
					VISIT 4	18FEB2014	15:52	2	Double Read
					VISIT 5	08APR2014	15:49	2	Double Read
					VISIT 6	14JUL2014	16:13	2	Double Read
					VISIT 7	28JAN2015	16:26	2	Double Read
					VISIT 8	14JAN2016	16:59	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	18SEP2013	15:42	N	Double Read
					VISIT 3A	13JAN2014	16:15	N	Double Read
					VISIT 3K	16JAN2014	17:29	N	Single Read
					VISIT 3L	05FEB2014	16:43	N	Single Read
					VISIT 4	18FEB2014	15:52	N	Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18SEP2013	15:42	N	Double Read
					VISIT 3A	13JAN2014	16:15	N	Double Read
					VISIT 3K	16JAN2014	17:29	N	Single Read
					VISIT 3L	05FEB2014	16:43	N	Single Read
					VISIT 4	18FEB2014	15:52	N	Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	18SEP2013	15:42	Y	Double Read
					VISIT 3A	13JAN2014	16:15	Y	Double Read
					VISIT 3K	16JAN2014	17:29	Y	Single Read
					VISIT 3L	05FEB2014	16:43	Y	Single Read
					VISIT 4	18FEB2014	15:52	N	Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26	N	Double Read
					VISIT 8	14JAN2016	16:59	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18SEP2013	15:42	N	Double Read
					VISIT 3A	13JAN2014	16:15	N	Double Read
					VISIT 3K	16JAN2014	17:29	N	Single Read
					VISIT 3L	05FEB2014	16:43	N	Single Read
					VISIT 4	18FEB2014	15:52	N	Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26	N	Double Read
					VISIT 8	14JAN2016	16:59	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	18SEP2013	15:42	N	Double Read
					VISIT 3A	13JAN2014	16:15	N	Double Read
					VISIT 3K	16JAN2014	17:29	N	Single Read
					VISIT 3L	05FEB2014	16:43	N	Single Read
					VISIT 4	18FEB2014	15:52	N	Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26	N	Double Read
					VISIT 8	14JAN2016	16:59	N	Double Read
Fracture	5_S		General		Baseline	18SEP2013	15:42	N	Double Read
					VISIT 3A	13JAN2014	16:15	N	Double Read
					VISIT 3K	16JAN2014	17:29	N	Single Read
					VISIT 3L	05FEB2014	16:43	N	Single Read
					VISIT 4	18FEB2014	15:52	N	Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Fracture	5_S		General		VISIT 7	28JAN2015	16:26	N	Double Read
					VISIT 8	14JAN2016	16:59	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18SEP2013	15:42	17.655	Double Read
					VISIT 3A	13JAN2014	16:15	17.515	Double Read
					VISIT 3K	16JAN2014	17:29	16.96	Single Read
					VISIT 3L	05FEB2014	16:43	17.84	Single Read
					VISIT 4	18FEB2014	15:52	17.655	Double Read
					VISIT 5	08APR2014	15:49	17.505	Double Read
					VISIT 6	14JUL2014	16:13	17.79	Double Read
					VISIT 7	28JAN2015	16:26	18.745	Double Read
					VISIT 8	14JAN2016	16:59	16.845	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18SEP2013	15:42	14.065	Double Read
					VISIT 3A	13JAN2014	16:15	14.655	Double Read
					VISIT 3K	16JAN2014	17:29	14.37	Single Read
					VISIT 3L	05FEB2014	16:43	13.47	Single Read
					VISIT 4	18FEB2014	15:52	14.5	Double Read
					VISIT 5	08APR2014	15:49	14.065	Double Read
					VISIT 6	14JUL2014	16:13	14.23	Double Read
					VISIT 7	28JAN2015	16:26	13.605	Double Read
					VISIT 8	14JAN2016	16:59	13.89	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18SEP2013	15:42		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18SEP2013	15:42	13.1978	Double Read
					VISIT 3A	13JAN2014	16:15	13.20665	Double Read
					VISIT 3K	16JAN2014	17:29	12.6433	Single Read
					VISIT 3L	05FEB2014	16:43	12.7929	Single Read
					VISIT 4	18FEB2014	15:52	13.2203	Double Read
					VISIT 5	08APR2014	15:49	13.74705	Double Read
					VISIT 6	14JUL2014	16:13	13.9387	Double Read
					VISIT 7	28JAN2015	16:26	13.30965	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18SEP2013	15:42	11.55705	Double Read
					VISIT 3A	13JAN2014	16:15	10.86075	Double Read
					VISIT 3K	16JAN2014	17:29	11.9293	Single Read
					VISIT 3L	05FEB2014	16:43	11.4832	Single Read
					VISIT 4	18FEB2014	15:52	11.3624	Double Read
					VISIT 5	08APR2014	15:49	11.57155	Double Read
					VISIT 6	14JUL2014	16:13	11.35585	Double Read
					VISIT 7	28JAN2015	16:26	11.01625	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	18SEP2013	15:42	N	Double Read
					VISIT 3A	13JAN2014	16:15	N	Double Read
					VISIT 3K	16JAN2014	17:29	N	Single Read
					VISIT 3L	05FEB2014	16:43	N	Single Read
					VISIT 4	18FEB2014	15:52	N	Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26	N	Double Read
					VISIT 8	14JAN2016	16:59	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18SEP2013	15:42	N	Double Read
					VISIT 3A	13JAN2014	16:15	N	Double Read
					VISIT 3K	16JAN2014	17:29	N	Single Read
					VISIT 3L	05FEB2014	16:43	N	Single Read
					VISIT 4	18FEB2014	15:52	N	Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26	N	Double Read
					VISIT 8	14JAN2016	16:59	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	18SEP2013	15:42	N	Double Read
					VISIT 3A	13JAN2014	16:15	N	Double Read
					VISIT 3K	16JAN2014	17:29	N	Single Read
					VISIT 3L	05FEB2014	16:43	N	Single Read
					VISIT 4	18FEB2014	15:52	N	Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26	N	Double Read
					VISIT 8	14JAN2016	16:59	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18SEP2013	15:42	N	Double Read
					VISIT 3A	13JAN2014	16:15	N	Double Read
					VISIT 3K	16JAN2014	17:29	N	Single Read
					VISIT 3L	05FEB2014	16:43	N	Single Read
					VISIT 4	18FEB2014	15:52	N	Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26	N	Double Read
					VISIT 8	14JAN2016	16:59	N	Double Read
Normal lordotic LS	5_S		General		Baseline	18SEP2013	15:42	Y	Double Read
					VISIT 3A	13JAN2014	16:15	Y	Double Read
					VISIT 3K	16JAN2014	17:29	Y	Single Read
					VISIT 3L	05FEB2014	16:43	Y	Single Read
					VISIT 4	18FEB2014	15:52	Y	Double Read
					VISIT 5	08APR2014	15:49	Y	Double Read
					VISIT 6	14JUL2014	16:13	Y	Double Read
					VISIT 7	28JAN2015	16:26	Y	Double Read
					VISIT 8	14JAN2016	16:59	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49	0	Double Read
					VISIT 6	14JUL2014	16:13	0	Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	18SEP2013	15:42	2	Double Read
					VISIT 3A	13JAN2014	16:15	1	Double Read
					VISIT 3K	16JAN2014	17:29	1	Single Read
					VISIT 3L	05FEB2014	16:43	1	Single Read
					VISIT 4	18FEB2014	15:52	2	Double Read
					VISIT 5	08APR2014	15:49	1	Double Read
					VISIT 6	14JUL2014	16:13	1	Double Read
					VISIT 7	28JAN2015	16:26	2	Double Read
					VISIT 8	14JAN2016	16:59	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18SEP2013	15:42	0	Double Read
					VISIT 3A	13JAN2014	16:15	0	Double Read
					VISIT 3K	16JAN2014	17:29	0	Single Read
					VISIT 3L	05FEB2014	16:43	0	Single Read
					VISIT 4	18FEB2014	15:52	0	Double Read
					VISIT 5	08APR2014	15:49	0	Double Read
					VISIT 6	14JUL2014	16:13	0	Double Read
					VISIT 7	28JAN2015	16:26	0	Double Read
					VISIT 8	14JAN2016	16:59	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	18SEP2013	15:42	N	Double Read
					VISIT 3A	13JAN2014	16:15	N	Double Read
					VISIT 3K	16JAN2014	17:29	N	Single Read
					VISIT 3L	05FEB2014	16:43	N	Single Read
					VISIT 4	18FEB2014	15:52	N	Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18SEP2013	15:42	N	Double Read
					VISIT 3A	13JAN2014	16:15	N	Double Read
					VISIT 3K	16JAN2014	17:29	N	Single Read
					VISIT 3L	05FEB2014	16:43	N	Single Read
					VISIT 4	18FEB2014	15:52	N	Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26	N	Double Read
Relevant scoliosis	5_S		General		Baseline	18SEP2013	15:42	N	Double Read
					VISIT 3A	13JAN2014	16:15	N	Double Read
					VISIT 3K	16JAN2014	17:29	N	Single Read
					VISIT 3L	05FEB2014	16:43	N	Single Read
					VISIT 4	18FEB2014	15:52	N	Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15	N	Double Read
					VISIT 3K	16JAN2014	17:29	N	Single Read
					VISIT 3L	05FEB2014	16:43	N	Single Read
					VISIT 4	18FEB2014	15:52	N	Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	18SEP2013	15:42	N	Double Read
					VISIT 3A	13JAN2014	16:15	N	Double Read
					VISIT 3K	16JAN2014	17:29	N	Single Read
					VISIT 3L	05FEB2014	16:43	N	Single Read
					VISIT 4	18FEB2014	15:52	N	Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18SEP2013	15:42	N	Double Read
					VISIT 3A	13JAN2014	16:15	N	Double Read
					VISIT 3K	16JAN2014	17:29	N	Single Read
					VISIT 3L	05FEB2014	16:43	N	Single Read
					VISIT 4	18FEB2014	15:52	N	Double Read
					VISIT 5	08APR2014	15:49	N	Double Read
					VISIT 6	14JUL2014	16:13	N	Double Read
					VISIT 7	28JAN2015	16:26	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18SEP2013	15:42	87.89792	Double Read
					VISIT 3A	13JAN2014	16:15	73.60768	Double Read
					VISIT 3K	16JAN2014	17:29	71.59648	Single Read
					VISIT 3L	05FEB2014	16:43	70.73056	Single Read
					VISIT 4	18FEB2014	15:52	75.37712	Double Read
					VISIT 5	08APR2014	15:49	74.67728	Double Read
					VISIT 6	14JUL2014	16:13	68.72064	Double Read
					VISIT 7	28JAN2015	16:26	73.86832	Double Read
					VISIT 8	14JAN2016	16:59	74.62016	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29	82.69472	Single Read
					VISIT 3L	05FEB2014	16:43	74.79104	Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18SEP2013	15:42	122.0944	Double Read
					VISIT 3A	13JAN2014	16:15	104.65184	Double Read
					VISIT 3K	16JAN2014	17:29	107.39584	Single Read
					VISIT 3L	05FEB2014	16:43	110.28192	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 4	18FEB2014	15:52	104.71312	Double Read
					VISIT 5	08APR2014	15:49	109.37104	Double Read
					VISIT 6	14JUL2014	16:13	107.86176	Double Read
					VISIT 7	28JAN2015	16:26	109.0568	Double Read
					VISIT 8	14JAN2016	16:59	109.11328	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29	119.35296	Single Read
					VISIT 3L	05FEB2014	16:43	131.02336	Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29	equal	Single Read
					VISIT 3L	05FEB2014	16:43	equal	Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29	equal	Single Read
					VISIT 3L	05FEB2014	16:43	equal	Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		VISIT 6	14JUL2014	16:13	lower	Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	18SEP2013	15:42	lower	Double Read
					VISIT 3A	13JAN2014	16:15	lower	Double Read
					VISIT 3K	16JAN2014	17:29	lower	Single Read
					VISIT 3L	05FEB2014	16:43	lower	Single Read
					VISIT 4	18FEB2014	15:52	lower	Double Read
					VISIT 5	08APR2014	15:49	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		VISIT 6	14JUL2014	16:13	lower	Double Read
					VISIT 7	28JAN2015	16:26	lower	Double Read
					VISIT 8	14JAN2016	16:59	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29	equal	Single Read
					VISIT 3L	05FEB2014	16:43	equal	Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 8	14JAN2016	16:59		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29	equal	Single Read
					VISIT 3L	05FEB2014	16:43	equal	Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18SEP2013	15:42	7.8866247664	Double Read
					VISIT 3A	13JAN2014	16:15	9.4700186852	Double Read
					VISIT 3K	16JAN2014	17:29	10.599626295	Single Read
					VISIT 3L	05FEB2014	16:43	8.7575199592	Single Read
					VISIT 4	18FEB2014	15:52	11.014635637	Double Read
					VISIT 5	08APR2014	15:49	8.1535586886	Double Read
					VISIT 6	14JUL2014	16:13	9.7948224902	Double Read
					VISIT 7	28JAN2015	16:26	12.098216409	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	14JAN2016	16:59	9.72264990658	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29	11.8906064209	Single Read
					VISIT 3L	05FEB2014	16:43	3.55586206897	Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18SEP2013	15:42	2.20824868354	Double Read
					VISIT 3A	13JAN2014	16:15	8.94626804823	Double Read
					VISIT 3K	16JAN2014	17:29	14.4046203499	Single Read
					VISIT 3L	05FEB2014	16:43	2.89903855954	Single Read
					VISIT 4	18FEB2014	15:52	8.57538984204	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 5	08APR2014	15:49	5.36775947002	Double Read
					VISIT 6	14JUL2014	16:13	4.14266689315	Double Read
					VISIT 7	28JAN2015	16:26	3.15101070155	Double Read
					VISIT 8	14JAN2016	16:59	7.47409546456	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29	2.98963818583	Single Read
					VISIT 3L	05FEB2014	16:43	1.81189740105	Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18SEP2013	15:42	21548.0	Double Read
					VISIT 3A	13JAN2014	16:15	21209.0	Double Read
					VISIT 3K	16JAN2014	17:29	21688	Single Read
					VISIT 3L	05FEB2014	16:43	21466	Single Read
					VISIT 4	18FEB2014	15:52	21086.0	Double Read
					VISIT 5	08APR2014	15:49	21536.0	Double Read
					VISIT 6	14JUL2014	16:13	20791.0	Double Read
					VISIT 7	28JAN2015	16:26	22184.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	14JAN2016	16:59	20098.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29		Single Read
					VISIT 3L	05FEB2014	16:43		Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	18SEP2013	15:42		Double Read
					VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29	13410	Single Read
					VISIT 3L	05FEB2014	16:43	11943	Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18SEP2013	15:42	20693.5	Double Read
					VISIT 3A	13JAN2014	16:15	20001.5	Double Read
					VISIT 3K	16JAN2014	17:29	21638	Single Read
					VISIT 3L	05FEB2014	16:43	19078	Single Read
					VISIT 4	18FEB2014	15:52	20939.5	Double Read
					VISIT 5	08APR2014	15:49	19885.0	Double Read
					VISIT 6	14JUL2014	16:13	20726.0	Double Read
					VISIT 7	28JAN2015	16:26	20415.5	Double Read
					VISIT 8	14JAN2016	16:59	20129.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	18SEP2013	15:42		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0121 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 3A	13JAN2014	16:15		Double Read
					VISIT 3K	16JAN2014	17:29	8228	Single Read
					VISIT 3L	05FEB2014	16:43	7135	Single Read
					VISIT 4	18FEB2014	15:52		Double Read
					VISIT 5	08APR2014	15:49		Double Read
					VISIT 6	14JUL2014	16:13		Double Read
					VISIT 7	28JAN2015	16:26		Double Read
					VISIT 8	14JAN2016	16:59		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	25SEP2013	16:19	4	Double Read
					VISIT 3A	16DEC2013	17:13	4	Double Read
					VISIT 3K	19DEC2013	17:11	4	Single Read
					VISIT 3L	09JAN2014	17:10	4	Single Read
					VISIT 4	29JAN2014	16:29	3	Double Read
					VISIT 5	18MAR2014	16:44	4	Double Read
					VISIT 6	11JUN2014	15:53	4	Double Read
					VISIT 7	17DEC2014	17:11	2	Double Read
					VISIT 8	16DEC2015	16:08	3	Double Read
					VISIT 11	19DEC2018	15:45	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25SEP2013	16:19	2	Double Read
					VISIT 3A	16DEC2013	17:13	2	Double Read
					VISIT 3K	19DEC2013	17:11	3	Single Read
					VISIT 3L	09JAN2014	17:10	3	Single Read
					VISIT 4	29JAN2014	16:29	2	Double Read
					VISIT 5	18MAR2014	16:44	2	Double Read
					VISIT 6	11JUN2014	15:53	2	Double Read
					VISIT 7	17DEC2014	17:11	2	Double Read
					VISIT 8	16DEC2015	16:08	2	Double Read
					VISIT 11	19DEC2018	15:45	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	25SEP2013	16:19		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	25SEP2013	16:19	N	Double Read
					VISIT 3A	16DEC2013	17:13	N	Double Read
					VISIT 3K	19DEC2013	17:11	N	Single Read
					VISIT 3L	09JAN2014	17:10	N	Single Read
					VISIT 4	29JAN2014	16:29	N	Double Read
					VISIT 5	18MAR2014	16:44	N	Double Read
					VISIT 6	11JUN2014	15:53	N	Double Read
					VISIT 7	17DEC2014	17:11	N	Double Read
					VISIT 8	16DEC2015	16:08	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25SEP2013	16:19	N	Double Read
					VISIT 3A	16DEC2013	17:13	N	Double Read
					VISIT 3K	19DEC2013	17:11	N	Single Read
					VISIT 3L	09JAN2014	17:10	N	Single Read
					VISIT 4	29JAN2014	16:29	N	Double Read
					VISIT 5	18MAR2014	16:44	N	Double Read
					VISIT 6	11JUN2014	15:53	N	Double Read
					VISIT 7	17DEC2014	17:11	N	Double Read
					VISIT 8	16DEC2015	16:08	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	25SEP2013	16:19	Y	Double Read
					VISIT 3A	16DEC2013	17:13	Y	Double Read
					VISIT 3K	19DEC2013	17:11	Y	Single Read
					VISIT 3L	09JAN2014	17:10	Y	Single Read
					VISIT 4	29JAN2014	16:29	N	Double Read
					VISIT 5	18MAR2014	16:44	Y	Double Read
					VISIT 6	11JUN2014	15:53	Y	Double Read
					VISIT 7	17DEC2014	17:11	Y	Double Read
					VISIT 8	16DEC2015	16:08	Y	Double Read
					VISIT 11	19DEC2018	15:45	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25SEP2013	16:19	N	Double Read
					VISIT 3A	16DEC2013	17:13	N	Double Read
					VISIT 3K	19DEC2013	17:11	N	Single Read
					VISIT 3L	09JAN2014	17:10	N	Single Read
					VISIT 4	29JAN2014	16:29	N	Double Read
					VISIT 5	18MAR2014	16:44	N	Double Read
					VISIT 6	11JUN2014	15:53	N	Double Read
					VISIT 7	17DEC2014	17:11	N	Double Read
					VISIT 8	16DEC2015	16:08	N	Double Read
					VISIT 11	19DEC2018	15:45	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	25SEP2013	16:19	N	Double Read
					VISIT 3A	16DEC2013	17:13	N	Double Read
					VISIT 3K	19DEC2013	17:11	N	Single Read
					VISIT 3L	09JAN2014	17:10	N	Single Read
					VISIT 4	29JAN2014	16:29	N	Double Read
					VISIT 5	18MAR2014	16:44	N	Double Read
					VISIT 6	11JUN2014	15:53	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 7	17DEC2014	17:11	N	Double Read
					VISIT 8	16DEC2015	16:08	N	Double Read
					VISIT 11	19DEC2018	15:45	N	Double Read
Fracture	5_S		General		Baseline	25SEP2013	16:19	N	Double Read
					VISIT 3A	16DEC2013	17:13	N	Double Read
					VISIT 3K	19DEC2013	17:11	N	Single Read
					VISIT 3L	09JAN2014	17:10	N	Single Read
					VISIT 4	29JAN2014	16:29	N	Double Read
					VISIT 5	18MAR2014	16:44	N	Double Read
					VISIT 6	11JUN2014	15:53	N	Double Read
					VISIT 7	17DEC2014	17:11	N	Double Read
					VISIT 8	16DEC2015	16:08	N	Double Read
					VISIT 11	19DEC2018	15:45	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25SEP2013	16:19	10.255	Double Read
					VISIT 3A	16DEC2013	17:13	11.51	Double Read
					VISIT 3K	19DEC2013	17:11	13.43	Single Read
					VISIT 3L	09JAN2014	17:10	13.15	Single Read
					VISIT 4	29JAN2014	16:29	12.14	Double Read
					VISIT 5	18MAR2014	16:44	12.94	Double Read
					VISIT 6	11JUN2014	15:53	11.445	Double Read
					VISIT 7	17DEC2014	17:11	12.365	Double Read
					VISIT 8	16DEC2015	16:08	12.23	Double Read
					VISIT 11	19DEC2018	15:45	10.605	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25SEP2013	16:19	16.435	Double Read
					VISIT 3A	16DEC2013	17:13	15.865	Double Read
					VISIT 3K	19DEC2013	17:11	15.22	Single Read
					VISIT 3L	09JAN2014	17:10	15.98	Single Read
					VISIT 4	29JAN2014	16:29	16.785	Double Read
					VISIT 5	18MAR2014	16:44	15.66	Double Read
					VISIT 6	11JUN2014	15:53	15.17	Double Read
					VISIT 7	17DEC2014	17:11	16.18	Double Read
					VISIT 8	16DEC2015	16:08	15.055	Double Read
					VISIT 11	19DEC2018	15:45	15.82	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25SEP2013	16:19	6.25865	Double Read
					VISIT 3A	16DEC2013	17:13	5.970625	Double Read
					VISIT 3K	19DEC2013	17:11	6.99798	Single Read
					VISIT 3L	09JAN2014	17:10	7.91261	Single Read
					VISIT 4	29JAN2014	16:29	6.69871	Double Read
					VISIT 5	18MAR2014	16:44	6.673145	Double Read
					VISIT 6	11JUN2014	15:53	6.551315	Double Read
					VISIT 7	17DEC2014	17:11	5.35188	Double Read
					VISIT 8	16DEC2015	16:08	5.366625	Double Read
					VISIT 11	19DEC2018	15:45	5.349825	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25SEP2013	16:19	11.3764	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 3A	16DEC2013	17:13	11.08345	Double Read
					VISIT 3K	19DEC2013	17:11	11.4632	Single Read
					VISIT 3L	09JAN2014	17:10	10.9766	Single Read
					VISIT 4	29JAN2014	16:29	10.94825	Double Read
					VISIT 5	18MAR2014	16:44	11.4687	Double Read
					VISIT 6	11JUN2014	15:53	11.13875	Double Read
					VISIT 7	17DEC2014	17:11	11.0176	Double Read
					VISIT 8	16DEC2015	16:08	11.0111	Double Read
					VISIT 11	19DEC2018	15:45	11.2764	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	25SEP2013	16:19	N	Double Read
					VISIT 3A	16DEC2013	17:13	N	Double Read
					VISIT 3K	19DEC2013	17:11	N	Single Read
					VISIT 3L	09JAN2014	17:10	N	Single Read
					VISIT 4	29JAN2014	16:29	N	Double Read
					VISIT 5	18MAR2014	16:44	N	Double Read
					VISIT 6	11JUN2014	15:53	N	Double Read
					VISIT 7	17DEC2014	17:11	N	Double Read
					VISIT 8	16DEC2015	16:08	N	Double Read
					VISIT 11	19DEC2018	15:45	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25SEP2013	16:19	N	Double Read
					VISIT 3A	16DEC2013	17:13	N	Double Read
					VISIT 3K	19DEC2013	17:11	N	Single Read
					VISIT 3L	09JAN2014	17:10	N	Single Read
					VISIT 4	29JAN2014	16:29	N	Double Read
					VISIT 5	18MAR2014	16:44	N	Double Read
					VISIT 6	11JUN2014	15:53	N	Double Read
					VISIT 7	17DEC2014	17:11	N	Double Read
					VISIT 8	16DEC2015	16:08	N	Double Read
					VISIT 11	19DEC2018	15:45	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	25SEP2013	16:19	N	Double Read
					VISIT 3A	16DEC2013	17:13	N	Double Read
					VISIT 3K	19DEC2013	17:11	N	Single Read
					VISIT 3L	09JAN2014	17:10	N	Single Read
					VISIT 4	29JAN2014	16:29	N	Double Read
					VISIT 5	18MAR2014	16:44	N	Double Read
					VISIT 6	11JUN2014	15:53	N	Double Read
					VISIT 7	17DEC2014	17:11	N	Double Read
					VISIT 8	16DEC2015	16:08	N	Double Read
					VISIT 11	19DEC2018	15:45	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25SEP2013	16:19	N	Double Read
					VISIT 3A	16DEC2013	17:13	N	Double Read
					VISIT 3K	19DEC2013	17:11	N	Single Read
					VISIT 3L	09JAN2014	17:10	N	Single Read
					VISIT 4	29JAN2014	16:29	N	Double Read
					VISIT 5	18MAR2014	16:44	N	Double Read
					VISIT 6	11JUN2014	15:53	N	Double Read
					VISIT 7	17DEC2014	17:11	N	Double Read
					VISIT 8	16DEC2015	16:08	N	Double Read
					VISIT 11	19DEC2018	15:45	N	Double Read
Normal lordotic LS	5_S		General		Baseline	25SEP2013	16:19	Y	Double Read
					VISIT 3A	16DEC2013	17:13	Y	Double Read
					VISIT 3K	19DEC2013	17:11	Y	Single Read
					VISIT 3L	09JAN2014	17:10	Y	Single Read
					VISIT 4	29JAN2014	16:29	Y	Double Read
					VISIT 5	18MAR2014	16:44	Y	Double Read
					VISIT 6	11JUN2014	15:53	Y	Double Read
					VISIT 7	17DEC2014	17:11	Y	Double Read
					VISIT 8	16DEC2015	16:08	Y	Double Read
					VISIT 11	19DEC2018	15:45	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	25SEP2013	16:19	0	Double Read
					VISIT 3A	16DEC2013	17:13	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 3K	19DEC2013	17:11	0	Single Read
					VISIT 3L	09JAN2014	17:10	0	Single Read
					VISIT 4	29JAN2014	16:29	0	Double Read
					VISIT 5	18MAR2014	16:44	0	Double Read
					VISIT 6	11JUN2014	15:53	0	Double Read
					VISIT 7	17DEC2014	17:11	0	Double Read
					VISIT 8	16DEC2015	16:08	0	Double Read
					VISIT 11	19DEC2018	15:45	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25SEP2013	16:19	0	Double Read
					VISIT 3A	16DEC2013	17:13	0	Double Read
					VISIT 3K	19DEC2013	17:11	0	Single Read
					VISIT 3L	09JAN2014	17:10	0	Single Read
					VISIT 4	29JAN2014	16:29	0	Double Read
					VISIT 5	18MAR2014	16:44	0	Double Read
					VISIT 6	11JUN2014	15:53	0	Double Read
					VISIT 7	17DEC2014	17:11	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 8	16DEC2015	16:08	0	Double Read
					VISIT 11	19DEC2018	15:45	0	Double Read
					Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
					Baseline	25SEP2013	16:19	N	Double Read
					VISIT 3A	16DEC2013	17:13	N	Double Read
					VISIT 3K	19DEC2013	17:11	N	Single Read
					VISIT 3L	09JAN2014	17:10	N	Single Read
					VISIT 4	29JAN2014	16:29	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 5	18MAR2014	16:44	N	Double Read
					VISIT 6	11JUN2014	15:53	N	Double Read
					VISIT 7	17DEC2014	17:11	Y	Double Read
					VISIT 8	16DEC2015	16:08	N	Double Read
					VISIT 11	19DEC2018	15:45	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25SEP2013	16:19	N	Double Read
					VISIT 3A	16DEC2013	17:13	N	Double Read
					VISIT 3K	19DEC2013	17:11	N	Single Read
					VISIT 3L	09JAN2014	17:10	N	Single Read
					VISIT 4	29JAN2014	16:29	N	Double Read
					VISIT 5	18MAR2014	16:44	N	Double Read
					VISIT 6	11JUN2014	15:53	N	Double Read
					VISIT 7	17DEC2014	17:11	N	Double Read
					VISIT 8	16DEC2015	16:08	N	Double Read
Relevant scoliosis	5_S		General		VISIT 11	19DEC2018	15:45	N	Double Read
					Baseline	25SEP2013	16:19	N	Double Read
					VISIT 3A	16DEC2013	17:13	N	Double Read
					VISIT 3K	19DEC2013	17:11	N	Single Read
					VISIT 3L	09JAN2014	17:10	N	Single Read
					VISIT 4	29JAN2014	16:29	N	Double Read
					VISIT 5	18MAR2014	16:44	N	Double Read
					VISIT 6	11JUN2014	15:53	N	Double Read
					VISIT 7	17DEC2014	17:11	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		VISIT 8	16DEC2015	16:08	N	Double Read
					VISIT 11	19DEC2018	15:45	N	Double Read
					Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	25SEP2013	16:19	N	Double Read
					VISIT 3A	16DEC2013	17:13	N	Double Read
					VISIT 3K	19DEC2013	17:11	N	Single Read
					VISIT 3L	09JAN2014	17:10	N	Single Read
					VISIT 4	29JAN2014	16:29	N	Double Read
					VISIT 5	18MAR2014	16:44	N	Double Read
					VISIT 6	11JUN2014	15:53	N	Double Read
					VISIT 7	17DEC2014	17:11	N	Double Read
					VISIT 8	16DEC2015	16:08	N	Double Read
					VISIT 11	19DEC2018	15:45	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25SEP2013	16:19	N	Double Read
					VISIT 3A	16DEC2013	17:13	N	Double Read
					VISIT 3K	19DEC2013	17:11	N	Single Read
					VISIT 3L	09JAN2014	17:10	N	Single Read
					VISIT 4	29JAN2014	16:29	N	Double Read
					VISIT 5	18MAR2014	16:44	N	Double Read
					VISIT 6	11JUN2014	15:53	N	Double Read
					VISIT 7	17DEC2014	17:11	N	Double Read
					VISIT 8	16DEC2015	16:08	N	Double Read
					VISIT 11	19DEC2018	15:45	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 11	19DEC2018	15:45		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25SEP2013	16:19	83.55296	Double Read
					VISIT 3A	16DEC2013	17:13	74.38352	Double Read
					VISIT 3K	19DEC2013	17:11	76.656	Single Read
					VISIT 3L	09JAN2014	17:10	76.76032	Single Read
					VISIT 4	29JAN2014	16:29	83.76448	Double Read
					VISIT 5	18MAR2014	16:44	73.12144	Double Read
					VISIT 6	11JUN2014	15:53	75.38112	Double Read
					VISIT 7	17DEC2014	17:11	76.0112	Double Read
					VISIT 8	16DEC2015	16:08	84.072	Double Read
					VISIT 11	19DEC2018	15:45	73.6768	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11	82.56832	Single Read
					VISIT 3L	09JAN2014	17:10	79.58688	Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25SEP2013	16:19	96.58848	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 3A	16DEC2013	17:13	91.83088	Double Read
					VISIT 3K	19DEC2013	17:11	94.68896	Single Read
					VISIT 3L	09JAN2014	17:10	92.9856	Single Read
					VISIT 4	29JAN2014	16:29	88.69776	Double Read
					VISIT 5	18MAR2014	16:44	90.07232	Double Read
					VISIT 6	11JUN2014	15:53	87.85104	Double Read
					VISIT 7	17DEC2014	17:11	94.36576	Double Read
					VISIT 8	16DEC2015	16:08	90.00704	Double Read
					VISIT 11	19DEC2018	15:45	91.72816	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11	100.65504	Single Read
					VISIT 3L	09JAN2014	17:10	100.07456	Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11	equal	Single Read
					VISIT 3L	09JAN2014	17:10	equal	Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11	equal	Single Read
					VISIT 3L	09JAN2014	17:10	equal	Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	25SEP2013	16:19	lower	Double Read
					VISIT 3A	16DEC2013	17:13	lower	Double Read
					VISIT 3K	19DEC2013	17:11	lower	Single Read
					VISIT 3L	09JAN2014	17:10	lower	Single Read
					VISIT 4	29JAN2014	16:29	lower	Double Read
					VISIT 5	18MAR2014	16:44	lower	Double Read
					VISIT 6	11JUN2014	15:53	lower	Double Read
					VISIT 7	17DEC2014	17:11	equal	Double Read
					VISIT 8	16DEC2015	16:08	lower	Double Read
					VISIT 11	19DEC2018	15:45	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11	equal	Single Read
					VISIT 3L	09JAN2014	17:10	equal	Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11	equal	Single Read
					VISIT 3L	09JAN2014	17:10	equal	Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25SEP2013	16:19	4.73683030406	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	16DEC2013	17:13	7.8194937999	Double Read
					VISIT 3K	19DEC2013	17:11	4.6713096653	Single Read
					VISIT 3L	09JAN2014	17:10	11.315671819	Single Read
					VISIT 4	29JAN2014	16:29	2.6539697638	Double Read
					VISIT 5	18MAR2014	16:44	6.0703855953	Double Read
					VISIT 6	11JUN2014	15:53	7.0494309495	Double Read
					VISIT 7	17DEC2014	17:11	5.4130524885	Double Read
					VISIT 8	16DEC2015	16:08	10.313687786	Double Read
					VISIT 11	19DEC2018	15:45	4.4391574656	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11	4.2466451503	Single Read
					VISIT 3L	09JAN2014	17:10	2.6531408187	Single Read
					VISIT 4	29JAN2014	16:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25SEP2013	16:19	6.2170885000	Double Read
					VISIT 3A	16DEC2013	17:13	16.1938508578	Double Read
					VISIT 3K	19DEC2013	17:11	14.3819262782	Single Read
					VISIT 3L	09JAN2014	17:10	2.7744793613	Single Read
					VISIT 4	29JAN2014	16:29	6.03023611347	Double Read
					VISIT 5	18MAR2014	16:44	7.54675726176	Double Read
					VISIT 6	11JUN2014	15:53	5.8547103788	Double Read
					VISIT 7	17DEC2014	17:11	12.9777475794	Double Read
					VISIT 8	16DEC2015	16:08	18.7636487176	Double Read
					VISIT 11	19DEC2018	15:45	11.3979955835	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11	12.8758280958	Single Read
					VISIT 3L	09JAN2014	17:10	8.9689145575	Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	25SEP2013	16:19		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
Volume (mm ³) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25SEP2013	16:19	8037.0	Double Read
					VISIT 3A	16DEC2013	17:13	9590.5	Double Read
					VISIT 3K	19DEC2013	17:11	10030	Single Read
					VISIT 3L	09JAN2014	17:10	9982	Single Read
					VISIT 4	29JAN2014	16:29	9656.5	Double Read
					VISIT 5	18MAR2014	16:44	9779.0	Double Read
					VISIT 6	11JUN2014	15:53	9538.5	Double Read
					VISIT 7	17DEC2014	17:11	8940.0	Double Read
					VISIT 8	16DEC2015	16:08	8832.5	Double Read
Volume (mm ³) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11		Single Read
					VISIT 3L	09JAN2014	17:10		Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
Volume (mm ³) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0122 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	VISIT 3K	19DEC2013	17:11	10464	Single Read
					VISIT 3L	09JAN2014	17:10	11317	Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25SEP2013	16:19	16994.5	Double Read
					VISIT 3A	16DEC2013	17:13	17699.0	Double Read
					VISIT 3K	19DEC2013	17:11	16788	Single Read
					VISIT 3L	09JAN2014	17:10	17467	Single Read
					VISIT 4	29JAN2014	16:29	18079.5	Double Read
					VISIT 5	18MAR2014	16:44	17680.0	Double Read
					VISIT 6	11JUN2014	15:53	17596.5	Double Read
					VISIT 7	17DEC2014	17:11	18095.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	16DEC2015	16:08	16953.5	Double Read
					VISIT 11	19DEC2018	15:45	16367.5	Double Read
					Baseline	25SEP2013	16:19		Double Read
					VISIT 3A	16DEC2013	17:13		Double Read
					VISIT 3K	19DEC2013	17:11	6324	Single Read
					VISIT 3L	09JAN2014	17:10	6150	Single Read
					VISIT 4	29JAN2014	16:29		Double Read
					VISIT 5	18MAR2014	16:44		Double Read
					VISIT 6	11JUN2014	15:53		Double Read
					VISIT 7	17DEC2014	17:11		Double Read
					VISIT 8	16DEC2015	16:08		Double Read
					VISIT 11	19DEC2018	15:45		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	15SEP2014	16:20	2	Double Read
					VISIT 3A	18DEC2014	17:57	2	Double Read
					VISIT 4	28JAN2015	18:15	2	Double Read
					VISIT 6	02JUL2015	16:16	2	Double Read
					VISIT 7	17DEC2015	16:14	2	Double Read
					VISIT 8	07DEC2016	16:20	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	15SEP2014	16:20	4	Double Read
					VISIT 3A	18DEC2014	17:57	4	Double Read
					VISIT 4	28JAN2015	18:15	4	Double Read
					VISIT 6	02JUL2015	16:16	4	Double Read
					VISIT 7	17DEC2015	16:14	4	Double Read
					VISIT 8	07DEC2016	16:20	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	15SEP2014	16:20	3	Double Read
					VISIT 3A	18DEC2014	17:57	2	Double Read
					VISIT 4	28JAN2015	18:15	3	Double Read
					VISIT 6	02JUL2015	16:16	3	Double Read
					VISIT 7	17DEC2015	16:14	3	Double Read
					VISIT 8	07DEC2016	16:20	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read
					VISIT 8	07DEC2016	16:20	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 8	07DEC2016	16:20	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read
					VISIT 8	07DEC2016	16:20	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read
					VISIT 8	07DEC2016	16:20	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	15SEP2014	16:20	Y	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	Y	Double Read
					VISIT 7	17DEC2015	16:14	Y	Double Read
					VISIT 8	07DEC2016	16:20	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read
					VISIT 8	07DEC2016	16:20	Y	Double Read
Extradiscal fluid collection	4_5		General		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	4_5		General		VISIT 8	07DEC2016	16:20	N	Double Read
Fracture	4_5		General		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read
					VISIT 8	07DEC2016	16:20	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	15SEP2014	16:20	13.84	Double Read
					VISIT 3A	18DEC2014	17:57	13.585	Double Read
					VISIT 4	28JAN2015	18:15	14.825	Double Read
					VISIT 6	02JUL2015	16:16	13.14	Double Read
					VISIT 7	17DEC2015	16:14	13.3	Double Read
					VISIT 8	07DEC2016	16:20	12.445	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	15SEP2014	16:20	14.91	Double Read
					VISIT 3A	18DEC2014	17:57	15.035	Double Read
					VISIT 4	28JAN2015	18:15	16.16	Double Read
					VISIT 6	02JUL2015	16:16	16.235	Double Read
					VISIT 7	17DEC2015	16:14	15.96	Double Read
					VISIT 8	07DEC2016	16:20	13.99	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	15SEP2014	16:20	15.1	Double Read
					VISIT 3A	18DEC2014	17:57	15.26	Double Read
					VISIT 4	28JAN2015	18:15	15.955	Double Read
					VISIT 6	02JUL2015	16:16	15.055	Double Read
					VISIT 7	17DEC2015	16:14	15.25	Double Read
					VISIT 8	07DEC2016	16:20	14.5	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	15SEP2014	16:20	10.517765	Double Read
					VISIT 3A	18DEC2014	17:57	10.417795	Double Read
					VISIT 4	28JAN2015	18:15	10.3756	Double Read
					VISIT 6	02JUL2015	16:16	10.5119	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	VISIT 7	17DEC2015	16:14	10.9235	Double Read
					VISIT 8	07DEC2016	16:20	10.7826	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	15SEP2014	16:20	11.8324	Double Read
					VISIT 3A	18DEC2014	17:57	11.8585	Double Read
					VISIT 4	28JAN2015	18:15	11.43425	Double Read
					VISIT 6	02JUL2015	16:16	11.9203	Double Read
					VISIT 7	17DEC2015	16:14	11.9424	Double Read
					VISIT 8	07DEC2016	16:20	11.45285	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	15SEP2014	16:20	13.79895	Double Read
					VISIT 3A	18DEC2014	17:57	10.296285	Double Read
					VISIT 4	28JAN2015	18:15	13.0203	Double Read
					VISIT 6	02JUL2015	16:16	13.44985	Double Read
					VISIT 7	17DEC2015	16:14	13.78405	Double Read
					VISIT 8	07DEC2016	16:20	12.56895	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read
					VISIT 8	07DEC2016	16:20	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read
					VISIT 8	07DEC2016	16:20	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read
					VISIT 8	07DEC2016	16:20	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read
					VISIT 8	07DEC2016	16:20	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read
					VISIT 8	07DEC2016	16:20	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read
					VISIT 8	07DEC2016	16:20	N	Double Read
Normal lordotic LS	4_5		General		Baseline	15SEP2014	16:20	Y	Double Read
					VISIT 3A	18DEC2014	17:57	Y	Double Read
					VISIT 4	28JAN2015	18:15	Y	Double Read
					VISIT 6	02JUL2015	16:16	Y	Double Read
					VISIT 7	17DEC2015	16:14	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	4_5		General		VISIT 8	07DEC2016	16:20	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	15SEP2014	16:20	0	Double Read
					VISIT 3A	18DEC2014	17:57	0	Double Read
					VISIT 4	28JAN2015	18:15	0	Double Read
					VISIT 6	02JUL2015	16:16	0	Double Read
					VISIT 7	17DEC2015	16:14	0	Double Read
					VISIT 8	07DEC2016	16:20	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	15SEP2014	16:20	0	Double Read
					VISIT 3A	18DEC2014	17:57	0	Double Read
					VISIT 4	28JAN2015	18:15	0	Double Read
					VISIT 6	02JUL2015	16:16	0	Double Read
					VISIT 7	17DEC2015	16:14	0	Double Read
					VISIT 8	07DEC2016	16:20	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	15SEP2014	16:20	0	Double Read
					VISIT 3A	18DEC2014	17:57	0	Double Read
					VISIT 4	28JAN2015	18:15	0	Double Read
					VISIT 6	02JUL2015	16:16	0	Double Read
					VISIT 7	17DEC2015	16:14	0	Double Read
					VISIT 8	07DEC2016	16:20	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read
					VISIT 8	07DEC2016	16:20	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	07DEC2016	16:20	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read
					VISIT 8	07DEC2016	16:20	N	Double Read
Relevant scoliosis	4_5		General		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read
					VISIT 8	07DEC2016	16:20	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read
					VISIT 8	07DEC2016	16:20	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read
					VISIT 7	17DEC2015	16:14	N	Double Read
					VISIT 8	07DEC2016	16:20	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	15SEP2014	16:20	N	Double Read
					VISIT 3A	18DEC2014	17:57	N	Double Read
					VISIT 4	28JAN2015	18:15	N	Double Read
					VISIT 6	02JUL2015	16:16	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	17DEC2015	16:14	N	Double Read
					VISIT 8	07DEC2016	16:20	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	15SEP2014	16:20	93.71536	Double Read
					VISIT 3A	18DEC2014	17:57	96.07184	Double Read
					VISIT 4	28JAN2015	18:15	88.88176	Double Read
					VISIT 6	02JUL2015	16:16	94.91248	Double Read
					VISIT 7	17DEC2015	16:14	95.63088	Double Read
					VISIT 8	07DEC2016	16:20	93.30512	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	15SEP2014	16:20	69.32896	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	18DEC2014	17:57	66.724	Double Read
					VISIT 4	28JAN2015	18:15	68.70112	Double Read
					VISIT 6	02JUL2015	16:16	73.01024	Double Read
					VISIT 7	17DEC2015	16:14	76.5296	Double Read
					VISIT 8	07DEC2016	16:20	69.92544	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	15SEP2014	16:20	83.55648	Double Read
					VISIT 3A	18DEC2014	17:57	78.0352	Double Read
					VISIT 4	28JAN2015	18:15	79.97536	Double Read
					VISIT 6	02JUL2015	16:16	79.45968	Double Read
					VISIT 7	17DEC2015	16:14	80.31728	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	07DEC2016	16:20	75.83504	Double Read
					Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	15SEP2014	16:20	lower	Double Read
					VISIT 3A	18DEC2014	17:57	lower	Double Read
					VISIT 4	28JAN2015	18:15	lower	Double Read
					VISIT 6	02JUL2015	16:16	lower	Double Read
					VISIT 7	17DEC2015	16:14	lower	Double Read
					VISIT 8	07DEC2016	16:20	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	15SEP2014	16:20	lower	Double Read
					VISIT 3A	18DEC2014	17:57	lower	Double Read
					VISIT 4	28JAN2015	18:15	lower	Double Read
					VISIT 6	02JUL2015	16:16	lower	Double Read
					VISIT 7	17DEC2015	16:14	lower	Double Read
					VISIT 8	07DEC2016	16:20	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	15SEP2014	16:20	3.67111941566	Double Read
					VISIT 3A	18DEC2014	17:57	5.74146424325	Double Read
					VISIT 4	28JAN2015	18:15	11.8056735179	Double Read
					VISIT 6	02JUL2015	16:16	9.53136062511	Double Read
					VISIT 7	17DEC2015	16:14	3.32936979786	Double Read
					VISIT 8	07DEC2016	16:20	5.1299473416	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	15SEP2014	16:20	8.56449804655	Double Read
					VISIT 3A	18DEC2014	17:57	8.60880584338	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 4	28JAN2015	18:15	7.6891931374	Double Read
					VISIT 6	02JUL2015	16:16	12.596833701	Double Read
					VISIT 7	17DEC2015	16:14	12.241664684	Double Read
					VISIT 8	07DEC2016	16:20	7.8232648207	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	15SEP2014	16:20	10.092862238	Double Read
					VISIT 3A	18DEC2014	17:57	6.1434822490	Double Read
					VISIT 4	28JAN2015	18:15	15.554883642	Double Read
					VISIT 6	02JUL2015	16:16	11.531999320	Double Read
					VISIT 7	17DEC2015	16:14	10.107368778	Double Read
					VISIT 8	07DEC2016	16:20	11.154523526	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	15SEP2014	16:20	13645.0	Double Read
					VISIT 3A	18DEC2014	17:57	12824.0	Double Read
					VISIT 4	28JAN2015	18:15	14632.5	Double Read
					VISIT 6	02JUL2015	16:16	13494.5	Double Read
					VISIT 7	17DEC2015	16:14	13919.5	Double Read
					VISIT 8	07DEC2016	16:20	13359.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	VISIT 8	07DEC2016	16:20		Double Read
Volume (mm ³) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	15SEP2014	16:20	17946.5	Double Read
					VISIT 3A	18DEC2014	17:57	17557.5	Double Read
					VISIT 4	28JAN2015	18:15	19088.0	Double Read
					VISIT 6	02JUL2015	16:16	18937.5	Double Read
					VISIT 7	17DEC2015	16:14	19449.0	Double Read
					VISIT 8	07DEC2016	16:20	18272.0	Double Read
Volume (mm ³) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
Volume (mm ³) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read
					VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read
Volume (mm ³) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	15SEP2014	16:20	22529.5	Double Read
					VISIT 3A	18DEC2014	17:57	21617.0	Double Read
					VISIT 4	28JAN2015	18:15	23634.0	Double Read
					VISIT 6	02JUL2015	16:16	22518.0	Double Read
					VISIT 7	17DEC2015	16:14	22459.5	Double Read
					VISIT 8	07DEC2016	16:20	21309.0	Double Read
Volume (mm ³) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	15SEP2014	16:20		Double Read
					VISIT 3A	18DEC2014	17:57		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0123 Age=50 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	28JAN2015	18:15		Double Read
					VISIT 6	02JUL2015	16:16		Double Read
					VISIT 7	17DEC2015	16:14		Double Read
					VISIT 8	07DEC2016	16:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0124 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	05NOV2014	16:22		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	05NOV2014	16:22	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	05NOV2014	16:22	1	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	05NOV2014	16:22		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	05NOV2014	16:22	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	05NOV2014	16:22	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	05NOV2014	16:22		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	05NOV2014	16:22	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	05NOV2014	16:22	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	05NOV2014	16:22	N	Double Read
Fracture	5_S		General		Baseline	05NOV2014	16:22	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	05NOV2014	16:22		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	05NOV2014	16:22	14.885	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	05NOV2014	16:22	15.54	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0124 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	05NOV2014	16:22		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	05NOV2014	16:22	8.962025	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	05NOV2014	16:22	11.8327	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	05NOV2014	16:22		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	05NOV2014	16:22	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	05NOV2014	16:22	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	05NOV2014	16:22		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	05NOV2014	16:22	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	05NOV2014	16:22	N	Double Read
Normal lordotic LS	5_S		General		Baseline	05NOV2014	16:22	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	05NOV2014	16:22		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	05NOV2014	16:22	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0124 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	05NOV2014	16:22	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	05NOV2014	16:22		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	05NOV2014	16:22	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	05NOV2014	16:22	N	Double Read
Relevant scoliosis	5_S		General		Baseline	05NOV2014	16:22	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	05NOV2014	16:22		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	05NOV2014	16:22	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	05NOV2014	16:22	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	05NOV2014	16:22		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	05NOV2014	16:22		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	05NOV2014	16:22		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	05NOV2014	16:22		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	05NOV2014	16:22	72.32528	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	05NOV2014	16:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0124 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	05NOV2014	16:22		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	05NOV2014	16:22	109.75648	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	05NOV2014	16:22		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	05NOV2014	16:22		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	05NOV2014	16:22		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	05NOV2014	16:22		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	05NOV2014	16:22		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	05NOV2014	16:22		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	05NOV2014	16:22		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	05NOV2014	16:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0124 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	05NOV2014	16:22	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	05NOV2014	16:22		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	05NOV2014	16:22		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	05NOV2014	16:22		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	05NOV2014	16:22		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	05NOV2014	16:22		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	05NOV2014	16:22		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	05NOV2014	16:22		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	05NOV2014	16:22		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	05NOV2014	16:22	6.4648887379	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	05NOV2014	16:22		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	05NOV2014	16:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0124 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	05NOV2014	16:22	2.4064277221	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	05NOV2014	16:22		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	05NOV2014	16:22		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	05NOV2014	16:22		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	05NOV2014	16:22		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	05NOV2014	16:22		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	05NOV2014	16:22	12319.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	05NOV2014	16:22		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	05NOV2014	16:22		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	05NOV2014	16:22	15557.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	05NOV2014	16:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0125 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	06OCT2014	17:26	4	Double Read
					VISIT 4	19NOV2014	17:21	4	Double Read
					VISIT 6	25MAR2015	16:28	3	Double Read
					VISIT 7	30SEP2015	15:58	4	Double Read
					VISIT 8	28SEP2016	16:02	3	Double Read
					VISIT 11	02OCT2019	16:18	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	06OCT2014	17:26	4	Double Read
					VISIT 4	19NOV2014	17:21	4	Double Read
					VISIT 6	25MAR2015	16:28	3	Double Read
					VISIT 7	30SEP2015	15:58	3	Double Read
					VISIT 8	28SEP2016	16:02	3	Double Read
					VISIT 11	02OCT2019	16:18	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	06OCT2014	17:26	N	Double Read
					VISIT 4	19NOV2014	17:21	N	Double Read
					VISIT 6	25MAR2015	16:28	N	Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0125 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 11	02OCT2019	16:18	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	06OCT2014	17:26	N	Double Read
					VISIT 4	19NOV2014	17:21	N	Double Read
					VISIT 6	25MAR2015	16:28	N	Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02	N	Double Read
					VISIT 11	02OCT2019	16:18	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	06OCT2014	17:26	Y	Double Read
					VISIT 4	19NOV2014	17:21	Y	Double Read
					VISIT 6	25MAR2015	16:28	Y	Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02	Y	Double Read
					VISIT 11	02OCT2019	16:18	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	06OCT2014	17:26	N	Double Read
					VISIT 4	19NOV2014	17:21	N	Double Read
					VISIT 6	25MAR2015	16:28	N	Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02	N	Double Read
					VISIT 11	02OCT2019	16:18	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	06OCT2014	17:26	N	Double Read
					VISIT 4	19NOV2014	17:21	N	Double Read
					VISIT 6	25MAR2015	16:28	N	Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0125 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 11	02OCT2019	16:18	N	Double Read
Fracture	5_S		General		Baseline	06OCT2014	17:26	N	Double Read
					VISIT 4	19NOV2014	17:21	N	Double Read
					VISIT 6	25MAR2015	16:28	N	Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02	N	Double Read
					VISIT 11	02OCT2019	16:18	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	06OCT2014	17:26	16.24	Double Read
					VISIT 4	19NOV2014	17:21	14.565	Double Read
					VISIT 6	25MAR2015	16:28	14.07	Double Read
					VISIT 7	30SEP2015	15:58	14.095	Double Read
					VISIT 8	28SEP2016	16:02	14.24	Double Read
					VISIT 11	02OCT2019	16:18	13.25	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	06OCT2014	17:26	15.865	Double Read
					VISIT 4	19NOV2014	17:21	14.865	Double Read
					VISIT 6	25MAR2015	16:28	14.395	Double Read
					VISIT 7	30SEP2015	15:58	14.98	Double Read
					VISIT 8	28SEP2016	16:02	14.635	Double Read
					VISIT 11	02OCT2019	16:18	14.875	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0125 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	06OCT2014	17:26	7.97294	Double Read
					VISIT 4	19NOV2014	17:21	8.160085	Double Read
					VISIT 6	25MAR2015	16:28	7.32718	Double Read
					VISIT 7	30SEP2015	15:58	7.392935	Double Read
					VISIT 8	28SEP2016	16:02	7.39334	Double Read
					VISIT 11	02OCT2019	16:18	5.22191	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	06OCT2014	17:26	9.59187	Double Read
					VISIT 4	19NOV2014	17:21	8.065195	Double Read
					VISIT 6	25MAR2015	16:28	8.612355	Double Read
					VISIT 7	30SEP2015	15:58	8.40081	Double Read
					VISIT 8	28SEP2016	16:02	8.78674	Double Read
					VISIT 11	02OCT2019	16:18	7.064125	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	06OCT2014	17:26	N	Double Read
					VISIT 4	19NOV2014	17:21	N	Double Read
					VISIT 6	25MAR2015	16:28	N	Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02	N	Double Read
					VISIT 11	02OCT2019	16:18	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0125 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	06OCT2014	17:26	N	Double Read
					VISIT 4	19NOV2014	17:21	N	Double Read
					VISIT 6	25MAR2015	16:28	N	Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02	N	Double Read
					VISIT 11	02OCT2019	16:18	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	06OCT2014	17:26	N	Double Read
					VISIT 4	19NOV2014	17:21	N	Double Read
					VISIT 6	25MAR2015	16:28	N	Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02	N	Double Read
					VISIT 11	02OCT2019	16:18	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	06OCT2014	17:26	N	Double Read
					VISIT 4	19NOV2014	17:21	N	Double Read
					VISIT 6	25MAR2015	16:28	N	Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02	N	Double Read
					VISIT 11	02OCT2019	16:18	N	Double Read
Normal lordotic LS	5_S		General		Baseline	06OCT2014	17:26	N	Double Read
					VISIT 4	19NOV2014	17:21	N	Double Read
					VISIT 6	25MAR2015	16:28	N	Double Read
					VISIT 7	30SEP2015	15:58	Y	Double Read
					VISIT 8	28SEP2016	16:02	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0125 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	5_S		General		VISIT 11	02OCT2019	16:18	N	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	06OCT2014	17:26	2	Double Read
					VISIT 4	19NOV2014	17:21	2	Double Read
					VISIT 6	25MAR2015	16:28	2	Double Read
					VISIT 7	30SEP2015	15:58	2	Double Read
					VISIT 8	28SEP2016	16:02	2	Double Read
					VISIT 11	02OCT2019	16:18	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	06OCT2014	17:26	2	Double Read
					VISIT 4	19NOV2014	17:21	2	Double Read
					VISIT 6	25MAR2015	16:28	2	Double Read
					VISIT 7	30SEP2015	15:58	2	Double Read
					VISIT 8	28SEP2016	16:02	2	Double Read
					VISIT 11	02OCT2019	16:18	2	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	06OCT2014	17:26	N	Double Read
					VISIT 4	19NOV2014	17:21	N	Double Read
					VISIT 6	25MAR2015	16:28	N	Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0125 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 11	02OCT2019	16:18	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	06OCT2014	17:26	N	Double Read
					VISIT 4	19NOV2014	17:21	N	Double Read
					VISIT 6	25MAR2015	16:28	N	Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02	N	Double Read
					VISIT 11	02OCT2019	16:18	N	Double Read
Relevant scoliosis	5_S		General		Baseline	06OCT2014	17:26	N	Double Read
					VISIT 4	19NOV2014	17:21	N	Double Read
					VISIT 6	25MAR2015	16:28	N	Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02	N	Double Read
					VISIT 11	02OCT2019	16:18	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	06OCT2014	17:26	N	Double Read
					VISIT 4	19NOV2014	17:21	N	Double Read
					VISIT 6	25MAR2015	16:28	N	Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read
					VISIT 8	28SEP2016	16:02	N	Double Read
					VISIT 11	02OCT2019	16:18	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	06OCT2014	17:26	N	Double Read
					VISIT 4	19NOV2014	17:21	N	Double Read
					VISIT 6	25MAR2015	16:28	N	Double Read
					VISIT 7	30SEP2015	15:58	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0125 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	28SEP2016	16:02	N	Double Read
					VISIT 11	02OCT2019	16:18	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	06OCT2014	17:26	75.05248	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0125 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 4	19NOV2014	17:21	69.04432	Double Read
					VISIT 6	25MAR2015	16:28	72.51728	Double Read
					VISIT 7	30SEP2015	15:58	71.69696	Double Read
					VISIT 8	28SEP2016	16:02	72.42464	Double Read
					VISIT 11	02OCT2019	16:18	64.01088	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	06OCT2014	17:26	73.33584	Double Read
					VISIT 4	19NOV2014	17:21	75.71824	Double Read
					VISIT 6	25MAR2015	16:28	78.71792	Double Read
					VISIT 7	30SEP2015	15:58	76.50176	Double Read
					VISIT 8	28SEP2016	16:02	83.40624	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	02OCT2019	16:18	75.68752	Double Read
					Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0125 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0125 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	06OCT2014	17:26	equal	Double Read
					VISIT 4	19NOV2014	17:21	equal	Double Read
					VISIT 6	25MAR2015	16:28	equal	Double Read
					VISIT 7	30SEP2015	15:58	lower	Double Read
					VISIT 8	28SEP2016	16:02	lower	Double Read
					VISIT 11	02OCT2019	16:18	equal	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0125 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0125 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	06OCT2014	17:26	8.9385493460	Double Read
					VISIT 4	19NOV2014	17:21	8.2506268048	Double Read
					VISIT 6	25MAR2015	16:28	9.6823509427	Double Read
					VISIT 7	30SEP2015	15:58	8.5123424494	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0125 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	28SEP2016	16:02	8.58227280448	Double Read
					VISIT 11	02OCT2019	16:18	9.18690674368	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	06OCT2014	17:26	9.14916256155	Double Read
					VISIT 4	19NOV2014	17:21	7.63263461865	Double Read
					VISIT 6	25MAR2015	16:28	9.92685578394	Double Read
					VISIT 7	30SEP2015	15:58	12.9816884661	Double Read
					VISIT 8	28SEP2016	16:02	9.8635434007	Double Read
					VISIT 11	02OCT2019	16:18	5.97927637167	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0125 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	06OCT2014	17:26	15429.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0125 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 4	19NOV2014	17:21	15650.0	Double Read
					VISIT 6	25MAR2015	16:28	14843.0	Double Read
					VISIT 7	30SEP2015	15:58	15103.0	Double Read
					VISIT 8	28SEP2016	16:02	14304.5	Double Read
					VISIT 11	02OCT2019	16:18	11642.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	06OCT2014	17:26	19557.5	Double Read
					VISIT 4	19NOV2014	17:21	17936.0	Double Read
					VISIT 6	25MAR2015	16:28	17345.0	Double Read
					VISIT 7	30SEP2015	15:58	19635.5	Double Read
					VISIT 8	28SEP2016	16:02	18124.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	02OCT2019	16:18	17683.5	Double Read
					Baseline	06OCT2014	17:26		Double Read
					VISIT 4	19NOV2014	17:21		Double Read
					VISIT 6	25MAR2015	16:28		Double Read
					VISIT 7	30SEP2015	15:58		Double Read
					VISIT 8	28SEP2016	16:02		Double Read
					VISIT 11	02OCT2019	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	07OCT2014	16:49	3	Double Read
					VISIT 3A	07JAN2015	16:17	4	Double Read
					VISIT 4	16FEB2015	17:04	3	Double Read
					VISIT 6	07JUL2015	16:07	3	Double Read
					VISIT 7	12JAN2016	16:17	3	Double Read
					VISIT 8	11JAN2017	17:09	4	Double Read
					VISIT 11	11DEC2019	16:00	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	07OCT2014	16:49	3	Double Read
					VISIT 3A	07JAN2015	16:17	4	Double Read
					VISIT 4	16FEB2015	17:04	4	Double Read
					VISIT 6	07JUL2015	16:07	4	Double Read
					VISIT 7	12JAN2016	16:17	4	Double Read
					VISIT 8	11JAN2017	17:09	4	Double Read
					VISIT 11	11DEC2019	16:00	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	07OCT2014	16:49	1	Double Read
					VISIT 3A	07JAN2015	16:17	2	Double Read
					VISIT 4	16FEB2015	17:04	2	Double Read
					VISIT 6	07JUL2015	16:07	2	Double Read
					VISIT 7	12JAN2016	16:17	2	Double Read
					VISIT 8	11JAN2017	17:09	2	Double Read
					VISIT 11	11DEC2019	16:00	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	07OCT2014	16:49	N	Double Read
					VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read
					VISIT 7	12JAN2016	16:17	N	Double Read
					VISIT 8	11JAN2017	17:09	N	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	07OCT2014	16:49	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read
					VISIT 7	12JAN2016	16:17	N	Double Read
					VISIT 8	11JAN2017	17:09	N	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	07OCT2014	16:49	N	Double Read
					VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read
					VISIT 7	12JAN2016	16:17	N	Double Read
					VISIT 8	11JAN2017	17:09	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 11	11DEC2019	16:00	N	Double Read
					Baseline	07OCT2014	16:49	Y	Double Read
					VISIT 3A	07JAN2015	16:17	Y	Double Read
					VISIT 4	16FEB2015	17:04	Y	Double Read
					VISIT 6	07JUL2015	16:07	Y	Double Read
					VISIT 7	12JAN2016	16:17	Y	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		VISIT 8	11JAN2017	17:09	Y	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read
					Baseline	07OCT2014	16:49	Y	Double Read
					VISIT 3A	07JAN2015	16:17	Y	Double Read
					VISIT 4	16FEB2015	17:04	Y	Double Read
					VISIT 6	07JUL2015	16:07	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	12JAN2016	16:17	Y	Double Read
					VISIT 8	11JAN2017	17:09	Y	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read
					Baseline	07OCT2014	16:49	N	Double Read
					VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	12JAN2016	16:17	N	Double Read
					VISIT 8	11JAN2017	17:09	N	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	07OCT2014	16:49	N	Double Read
					VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read
					VISIT 7	12JAN2016	16:17	N	Double Read
					VISIT 8	11JAN2017	17:09	N	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read
Fracture	4_5		General		Baseline	07OCT2014	16:49	N	Double Read
					VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read
					VISIT 7	12JAN2016	16:17	N	Double Read
					VISIT 8	11JAN2017	17:09	N	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	07OCT2014	16:49	14.215	Double Read
					VISIT 3A	07JAN2015	16:17	14.555	Double Read
					VISIT 4	16FEB2015	17:04	13.06	Double Read
					VISIT 6	07JUL2015	16:07	12.795	Double Read
					VISIT 7	12JAN2016	16:17	13.385	Double Read
					VISIT 8	11JAN2017	17:09	14.08	Double Read
					VISIT 11	11DEC2019	16:00	11.955	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	07OCT2014	16:49	10.87	Double Read
					VISIT 3A	07JAN2015	16:17	11.67	Double Read
					VISIT 4	16FEB2015	17:04	11.135	Double Read
					VISIT 6	07JUL2015	16:07	10.145	Double Read
					VISIT 7	12JAN2016	16:17	10.06	Double Read
					VISIT 8	11JAN2017	17:09	10.47	Double Read
					VISIT 11	11DEC2019	16:00	10.42	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	07OCT2014	16:49	13.02	Double Read
					VISIT 3A	07JAN2015	16:17	13.285	Double Read
					VISIT 4	16FEB2015	17:04	12.18	Double Read
					VISIT 6	07JUL2015	16:07	12.32	Double Read
					VISIT 7	12JAN2016	16:17	12.7	Double Read
					VISIT 8	11JAN2017	17:09	13.2	Double Read
					VISIT 11	11DEC2019	16:00	12.805	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	07OCT2014	16:49	11.7786	Double Read
					VISIT 3A	07JAN2015	16:17	11.3305	Double Read
					VISIT 4	16FEB2015	17:04	9.26909	Double Read
					VISIT 6	07JUL2015	16:07	9.657725	Double Read
					VISIT 7	12JAN2016	16:17	9.83485	Double Read
					VISIT 8	11JAN2017	17:09	9.79785	Double Read
					VISIT 11	11DEC2019	16:00	9.40307	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	07OCT2014	16:49	9.354355	Double Read
					VISIT 3A	07JAN2015	16:17	8.755855	Double Read
					VISIT 4	16FEB2015	17:04	9.23453	Double Read
					VISIT 6	07JUL2015	16:07	9.164075	Double Read
					VISIT 7	12JAN2016	16:17	7.55562	Double Read
					VISIT 8	11JAN2017	17:09	9.62011	Double Read
					VISIT 11	11DEC2019	16:00	7.900785	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	07OCT2014	16:49	13.13915	Double Read
					VISIT 3A	07JAN2015	16:17	11.46315	Double Read
					VISIT 4	16FEB2015	17:04	11.71855	Double Read
					VISIT 6	07JUL2015	16:07	11.527	Double Read
					VISIT 7	12JAN2016	16:17	11.30055	Double Read
					VISIT 8	11JAN2017	17:09	12.06455	Double Read
					VISIT 11	11DEC2019	16:00	11.89445	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	07OCT2014	16:49	N	Double Read
					VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read
					VISIT 7	12JAN2016	16:17	N	Double Read
					VISIT 8	11JAN2017	17:09	N	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	07OCT2014	16:49	N	Double Read
					VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read
					VISIT 7	12JAN2016	16:17	N	Double Read
					VISIT 8	11JAN2017	17:09	N	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	07OCT2014	16:49	N	Double Read
					VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read
					VISIT 7	12JAN2016	16:17	N	Double Read
					VISIT 8	11JAN2017	17:09	N	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	07OCT2014	16:49	N	Double Read
					VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read
					VISIT 7	12JAN2016	16:17	N	Double Read
					VISIT 8	11JAN2017	17:09	N	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	07OCT2014	16:49	N	Double Read
					VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read
					VISIT 7	12JAN2016	16:17	N	Double Read
					VISIT 8	11JAN2017	17:09	N	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	07OCT2014	16:49	N	Double Read
					VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read
					VISIT 7	12JAN2016	16:17	N	Double Read
					VISIT 8	11JAN2017	17:09	N	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read
Normal lordotic LS	4_5		General		Baseline	07OCT2014	16:49	Y	Double Read
					VISIT 3A	07JAN2015	16:17	Y	Double Read
					VISIT 4	16FEB2015	17:04	Y	Double Read
					VISIT 6	07JUL2015	16:07	Y	Double Read
					VISIT 7	12JAN2016	16:17	Y	Double Read
					VISIT 8	11JAN2017	17:09	Y	Double Read
					VISIT 11	11DEC2019	16:00	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	07OCT2014	16:49	0	Double Read
					VISIT 3A	07JAN2015	16:17	0	Double Read
					VISIT 4	16FEB2015	17:04	0	Double Read
					VISIT 6	07JUL2015	16:07	0	Double Read
					VISIT 7	12JAN2016	16:17	0	Double Read
					VISIT 8	11JAN2017	17:09	0	Double Read
					VISIT 11	11DEC2019	16:00	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	07OCT2014	16:49	1	Double Read
					VISIT 3A	07JAN2015	16:17	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 4	16FEB2015	17:04	0	Double Read
					VISIT 6	07JUL2015	16:07	0	Double Read
					VISIT 7	12JAN2016	16:17	0	Double Read
					VISIT 8	11JAN2017	17:09	0	Double Read
					VISIT 11	11DEC2019	16:00	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	07OCT2014	16:49	0	Double Read
					VISIT 3A	07JAN2015	16:17	0	Double Read
					VISIT 4	16FEB2015	17:04	0	Double Read
					VISIT 6	07JUL2015	16:07	0	Double Read
					VISIT 7	12JAN2016	16:17	0	Double Read
					VISIT 8	11JAN2017	17:09	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 11	11DEC2019	16:00	0	Double Read
					Baseline	07OCT2014	16:49	N	Double Read
					VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read
					VISIT 7	12JAN2016	16:17	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	11JAN2017	17:09	N	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read
					Baseline	07OCT2014	16:49	N	Double Read
					VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	12JAN2016	16:17	N	Double Read
					VISIT 8	11JAN2017	17:09	N	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read
					Baseline	07OCT2014	16:49	N	Double Read
					VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read
					VISIT 7	12JAN2016	16:17	N	Double Read
					VISIT 8	11JAN2017	17:09	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	11JAN2017	17:09	N	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read
Relevant scoliosis	4_5		General		Baseline	07OCT2014	16:49	N	Double Read
					VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read
					VISIT 7	12JAN2016	16:17	N	Double Read
					VISIT 8	11JAN2017	17:09	N	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	07OCT2014	16:49	N	Double Read
					VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read
					VISIT 7	12JAN2016	16:17	N	Double Read
					VISIT 8	11JAN2017	17:09	N	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	07OCT2014	16:49	N	Double Read
					VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read
					VISIT 7	12JAN2016	16:17	N	Double Read
					VISIT 8	11JAN2017	17:09	N	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	07OCT2014	16:49	N	Double Read
					VISIT 3A	07JAN2015	16:17	N	Double Read
					VISIT 4	16FEB2015	17:04	N	Double Read
					VISIT 6	07JUL2015	16:07	N	Double Read
					VISIT 7	12JAN2016	16:17	N	Double Read
					VISIT 8	11JAN2017	17:09	N	Double Read
					VISIT 11	11DEC2019	16:00	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	07OCT2014	16:49	65.35808	Double Read
					VISIT 3A	07JAN2015	16:17	68.40624	Double Read
					VISIT 4	16FEB2015	17:04	65.91632	Double Read
					VISIT 6	07JUL2015	16:07	67.93664	Double Read
					VISIT 7	12JAN2016	16:17	73.27712	Double Read
					VISIT 8	11JAN2017	17:09	69.45776	Double Read
					VISIT 11	11DEC2019	16:00	66.78416	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	07OCT2014	16:49	68.536	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	07JAN2015	16:17	76.22544	Double Read
					VISIT 4	16FEB2015	17:04	71.3384	Double Read
					VISIT 6	07JUL2015	16:07	71.3856	Double Read
					VISIT 7	12JAN2016	16:17	72.09744	Double Read
					VISIT 8	11JAN2017	17:09	77.85792	Double Read
					VISIT 11	11DEC2019	16:00	73.00896	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	07OCT2014	16:49	95.59376	Double Read
					VISIT 3A	07JAN2015	16:17	94.88064	Double Read
					VISIT 4	16FEB2015	17:04	94.26512	Double Read
					VISIT 6	07JUL2015	16:07	97.70416	Double Read
					VISIT 7	12JAN2016	16:17	90.93136	Double Read
					VISIT 8	11JAN2017	17:09	94.25456	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	11DEC2019	16:00	86.67232	Double Read
					VISIT 3A	07JAN2015	16:17		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	07OCT2014	16:49	equal	Double Read
					VISIT 3A	07JAN2015	16:17	equal	Double Read
					VISIT 4	16FEB2015	17:04	equal	Double Read
					VISIT 6	07JUL2015	16:07	equal	Double Read
					VISIT 7	12JAN2016	16:17	equal	Double Read
					VISIT 8	11JAN2017	17:09	equal	Double Read
					VISIT 11	11DEC2019	16:00	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		VISIT 11	11DEC2019	16:00		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	07OCT2014	16:49	lower	Double Read
					VISIT 3A	07JAN2015	16:17	lower	Double Read
					VISIT 4	16FEB2015	17:04	lower	Double Read
					VISIT 6	07JUL2015	16:07	lower	Double Read
					VISIT 7	12JAN2016	16:17	lower	Double Read
					VISIT 8	11JAN2017	17:09	lower	Double Read
					VISIT 11	11DEC2019	16:00	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	07OCT2014	16:49	8.5947681331	Double Read
					VISIT 3A	07JAN2015	16:17	7.7790453541	Double Read
					VISIT 4	16FEB2015	17:04	7.7046305418	Double Read
					VISIT 6	07JUL2015	16:07	9.3547545439	Double Read
					VISIT 7	12JAN2016	16:17	7.8839137081	Double Read
					VISIT 8	11JAN2017	17:09	7.5679701036	Double Read
					VISIT 11	11DEC2019	16:00	10.548666553	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	07OCT2014	16:49	7.9578528962	Double Read
					VISIT 3A	07JAN2015	16:17	5.2318668252	Double Read
					VISIT 4	16FEB2015	17:04	8.7521318158	Double Read
					VISIT 6	07JUL2015	16:07	10.695940207	Double Read
					VISIT 7	12JAN2016	16:17	2.9309597418	Double Read
					VISIT 8	11JAN2017	17:09	4.9491353830	Double Read
					VISIT 11	11DEC2019	16:00	8.8233123832	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	07OCT2014	16:49	5.6621912688	Double Read
					VISIT 3A	07JAN2015	16:17	10.720421267	Double Read
					VISIT 4	16FEB2015	17:04	12.626689315	Double Read
					VISIT 6	07JUL2015	16:07	8.8330219126	Double Read
					VISIT 7	12JAN2016	16:17	6.3982741634	Double Read
					VISIT 8	11JAN2017	17:09	4.7359130287	Double Read
					VISIT 11	11DEC2019	16:00	10.101355529	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	07OCT2014	16:49	12010.5	Double Read
					VISIT 3A	07JAN2015	16:17	11675.0	Double Read
					VISIT 4	16FEB2015	17:04	10139.5	Double Read
					VISIT 6	07JUL2015	16:07	10605.0	Double Read
					VISIT 7	12JAN2016	16:17	10886.0	Double Read
					VISIT 8	11JAN2017	17:09	10819.5	Double Read
					VISIT 11	11DEC2019	16:00	9644.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	07OCT2014	16:49	10424.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	07JAN2015	16:17	10204.5	Double Read
					VISIT 4	16FEB2015	17:04	9357.5	Double Read
					VISIT 6	07JUL2015	16:07	9039.0	Double Read
					VISIT 7	12JAN2016	16:17	9468.5	Double Read
					VISIT 8	11JAN2017	17:09	8886.0	Double Read
					VISIT 11	11DEC2019	16:00	8344.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read
					VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	07OCT2014	16:49	12440.5	Double Read
					VISIT 3A	07JAN2015	16:17	12473.0	Double Read
					VISIT 4	16FEB2015	17:04	12155.5	Double Read
					VISIT 6	07JUL2015	16:07	11833.0	Double Read
					VISIT 7	12JAN2016	16:17	12996.0	Double Read
					VISIT 8	11JAN2017	17:09	12598.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	07OCT2014	16:49		Double Read
					VISIT 3A	07JAN2015	16:17		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0126 Age=38 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	16FEB2015	17:04		Double Read
					VISIT 6	07JUL2015	16:07		Double Read
					VISIT 7	12JAN2016	16:17		Double Read
					VISIT 8	11JAN2017	17:09		Double Read
					VISIT 11	11DEC2019	16:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	17OCT2014	16:03	4	Double Read
					VISIT 3A	08JAN2015	16:00	3	Double Read
					VISIT 4	19FEB2015	16:08	3	Double Read
					VISIT 6	01JUL2015	16:06	4	Double Read
					VISIT 7	13JAN2016	19:16	4	Double Read
					VISIT 8	11JAN2017	16:14	4	Double Read
					VISIT 11	18DEC2019	17:08	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17OCT2014	16:03	2	Double Read
					VISIT 3A	08JAN2015	16:00	2	Double Read
					VISIT 4	19FEB2015	16:08	2	Double Read
					VISIT 6	01JUL2015	16:06	2	Double Read
					VISIT 7	13JAN2016	19:16	1	Double Read
					VISIT 8	11JAN2017	16:14	2	Double Read
					VISIT 11	18DEC2019	17:08	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	17OCT2014	16:03	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	08JAN2015	16:00	N	Double Read
					VISIT 4	19FEB2015	16:08	Y	Double Read
					VISIT 6	01JUL2015	16:06	Y	Double Read
					VISIT 7	13JAN2016	19:16	N	Double Read
					VISIT 8	11JAN2017	16:14	N	Double Read
					VISIT 11	18DEC2019	17:08	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17OCT2014	16:03	N	Double Read
					VISIT 3A	08JAN2015	16:00	N	Double Read
					VISIT 4	19FEB2015	16:08	N	Double Read
					VISIT 6	01JUL2015	16:06	N	Double Read
					VISIT 7	13JAN2016	19:16	N	Double Read
					VISIT 8	11JAN2017	16:14	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	18DEC2019	17:08	N	Double Read
					Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
					Baseline	17OCT2014	16:03	Y	Double Read
					VISIT 3A	08JAN2015	16:00	Y	Double Read
					VISIT 4	19FEB2015	16:08	Y	Double Read
					VISIT 6	01JUL2015	16:06	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	13JAN2016	19:16	Y	Double Read
					VISIT 8	11JAN2017	16:14	Y	Double Read
					VISIT 11	18DEC2019	17:08	Y	Double Read
					Baseline	17OCT2014	16:03	N	Double Read
					VISIT 3A	08JAN2015	16:00	N	Double Read
					VISIT 4	19FEB2015	16:08	N	Double Read
					VISIT 6	01JUL2015	16:06	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	13JAN2016	19:16	N	Double Read
					VISIT 8	11JAN2017	16:14	N	Double Read
					VISIT 11	18DEC2019	17:08	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	17OCT2014	16:03	N	Double Read
					VISIT 3A	08JAN2015	16:00	N	Double Read
					VISIT 4	19FEB2015	16:08	N	Double Read
					VISIT 6	01JUL2015	16:06	N	Double Read
					VISIT 7	13JAN2016	19:16	N	Double Read
					VISIT 8	11JAN2017	16:14	N	Double Read
					VISIT 11	18DEC2019	17:08	N	Double Read
Fracture	5_S		General		Baseline	17OCT2014	16:03	N	Double Read
					VISIT 3A	08JAN2015	16:00	N	Double Read
					VISIT 4	19FEB2015	16:08	N	Double Read
					VISIT 6	01JUL2015	16:06	N	Double Read
					VISIT 7	13JAN2016	19:16	N	Double Read
					VISIT 8	11JAN2017	16:14	N	Double Read
					VISIT 11	18DEC2019	17:08	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	17OCT2014	16:03	15.36	Double Read
					VISIT 3A	08JAN2015	16:00	15.15	Double Read
					VISIT 4	19FEB2015	16:08	13.88	Double Read
					VISIT 6	01JUL2015	16:06	15.245	Double Read
					VISIT 7	13JAN2016	19:16	15.08	Double Read
					VISIT 8	11JAN2017	16:14	14.19	Double Read
					VISIT 11	18DEC2019	17:08	10.66	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	17OCT2014	16:03	14.8	Double Read
					VISIT 3A	08JAN2015	16:00	15.115	Double Read
					VISIT 4	19FEB2015	16:08	14.81	Double Read
					VISIT 6	01JUL2015	16:06	14.635	Double Read
					VISIT 7	13JAN2016	19:16	14.395	Double Read
					VISIT 8	11JAN2017	16:14	16.465	Double Read
					VISIT 11	18DEC2019	17:08	15.66	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	17OCT2014	16:03	11.21735	Double Read
					VISIT 3A	08JAN2015	16:00	8.118375	Double Read
					VISIT 4	19FEB2015	16:08	10.8708	Double Read
					VISIT 6	01JUL2015	16:06	11.2142	Double Read
					VISIT 7	13JAN2016	19:16	10.7649	Double Read
					VISIT 8	11JAN2017	16:14	9.269815	Double Read
					VISIT 11	18DEC2019	17:08	5.495825	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	17OCT2014	16:03	12.91155	Double Read
					VISIT 3A	08JAN2015	16:00	10.305385	Double Read
					VISIT 4	19FEB2015	16:08	12.23445	Double Read
					VISIT 6	01JUL2015	16:06	12.0749	Double Read
					VISIT 7	13JAN2016	19:16	12.7938	Double Read
					VISIT 8	11JAN2017	16:14	12.3685	Double Read
					VISIT 11	18DEC2019	17:08	13.25335	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	17OCT2014	16:03	N	Double Read
					VISIT 3A	08JAN2015	16:00	N	Double Read
					VISIT 4	19FEB2015	16:08	N	Double Read
					VISIT 6	01JUL2015	16:06	N	Double Read
					VISIT 7	13JAN2016	19:16	N	Double Read
					VISIT 8	11JAN2017	16:14	N	Double Read
					VISIT 11	18DEC2019	17:08	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17OCT2014	16:03	N	Double Read
					VISIT 3A	08JAN2015	16:00	N	Double Read
					VISIT 4	19FEB2015	16:08	N	Double Read
					VISIT 6	01JUL2015	16:06	N	Double Read
					VISIT 7	13JAN2016	19:16	N	Double Read
					VISIT 8	11JAN2017	16:14	N	Double Read
					VISIT 11	18DEC2019	17:08	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	17OCT2014	16:03	N	Double Read
					VISIT 3A	08JAN2015	16:00	N	Double Read
					VISIT 4	19FEB2015	16:08	N	Double Read
					VISIT 6	01JUL2015	16:06	N	Double Read
					VISIT 7	13JAN2016	19:16	N	Double Read
					VISIT 8	11JAN2017	16:14	N	Double Read
					VISIT 11	18DEC2019	17:08	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17OCT2014	16:03	N	Double Read
					VISIT 3A	08JAN2015	16:00	N	Double Read
					VISIT 4	19FEB2015	16:08	N	Double Read
					VISIT 6	01JUL2015	16:06	N	Double Read
					VISIT 7	13JAN2016	19:16	N	Double Read
					VISIT 8	11JAN2017	16:14	N	Double Read
					VISIT 11	18DEC2019	17:08	N	Double Read
Normal lordotic LS	5_S		General		Baseline	17OCT2014	16:03	Y	Double Read
					VISIT 3A	08JAN2015	16:00	Y	Double Read
					VISIT 4	19FEB2015	16:08	Y	Double Read
					VISIT 6	01JUL2015	16:06	Y	Double Read
					VISIT 7	13JAN2016	19:16	Y	Double Read
					VISIT 8	11JAN2017	16:14	Y	Double Read
					VISIT 11	18DEC2019	17:08	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	17OCT2014	16:03	0	Double Read
					VISIT 3A	08JAN2015	16:00	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	19FEB2015	16:08	0	Double Read
					VISIT 6	01JUL2015	16:06	0	Double Read
					VISIT 7	13JAN2016	19:16	0	Double Read
					VISIT 8	11JAN2017	16:14	1	Double Read
					VISIT 11	18DEC2019	17:08	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17OCT2014	16:03	0	Double Read
					VISIT 3A	08JAN2015	16:00	0	Double Read
					VISIT 4	19FEB2015	16:08	0	Double Read
					VISIT 6	01JUL2015	16:06	0	Double Read
					VISIT 7	13JAN2016	19:16	0	Double Read
					VISIT 8	11JAN2017	16:14	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 11	18DEC2019	17:08	0	Double Read
					Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
					Baseline	17OCT2014	16:03	N	Double Read
					VISIT 3A	08JAN2015	16:00	N	Double Read
					VISIT 4	19FEB2015	16:08	N	Double Read
					VISIT 6	01JUL2015	16:06	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	13JAN2016	19:16	N	Double Read
					VISIT 8	11JAN2017	16:14	N	Double Read
					VISIT 11	18DEC2019	17:08	N	Double Read
					Baseline	17OCT2014	16:03	N	Double Read
					VISIT 3A	08JAN2015	16:00	N	Double Read
					VISIT 4	19FEB2015	16:08	N	Double Read
					VISIT 6	01JUL2015	16:06	N	Double Read
					VISIT 7	13JAN2016	19:16	N	Double Read
					VISIT 8	11JAN2017	16:14	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	11JAN2017	16:14	N	Double Read
					VISIT 11	18DEC2019	17:08	N	Double Read
Relevant scoliosis	5_S		General		Baseline	17OCT2014	16:03	N	Double Read
					VISIT 3A	08JAN2015	16:00	N	Double Read
					VISIT 4	19FEB2015	16:08	N	Double Read
					VISIT 6	01JUL2015	16:06	N	Double Read
					VISIT 7	13JAN2016	19:16	N	Double Read
					VISIT 8	11JAN2017	16:14	N	Double Read
					VISIT 11	18DEC2019	17:08	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	17OCT2014	16:03	N	Double Read
					VISIT 3A	08JAN2015	16:00	N	Double Read
					VISIT 4	19FEB2015	16:08	N	Double Read
					VISIT 6	01JUL2015	16:06	N	Double Read
					VISIT 7	13JAN2016	19:16	N	Double Read
					VISIT 8	11JAN2017	16:14	N	Double Read
					VISIT 11	18DEC2019	17:08	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17OCT2014	16:03	N	Double Read
					VISIT 3A	08JAN2015	16:00	N	Double Read
					VISIT 4	19FEB2015	16:08	N	Double Read
					VISIT 6	01JUL2015	16:06	N	Double Read
					VISIT 7	13JAN2016	19:16	N	Double Read
					VISIT 8	11JAN2017	16:14	N	Double Read
					VISIT 11	18DEC2019	17:08	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	17OCT2014	16:03	71.14608	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	08JAN2015	16:00	76.04848	Double Read
					VISIT 4	19FEB2015	16:08	74.73392	Double Read
					VISIT 6	01JUL2015	16:06	74.12928	Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14	77.20624	Double Read
					VISIT 11	18DEC2019	17:08	73.1552	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	17OCT2014	16:03	109.44128	Double Read
					VISIT 3A	08JAN2015	16:00	113.75888	Double Read
					VISIT 4	19FEB2015	16:08	110.05104	Double Read
					VISIT 6	01JUL2015	16:06	112.30176	Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14	106.4312	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	18DEC2019	17:08	98.83088	Double Read
					VISIT 3A	08JAN2015	16:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 8	11JAN2017	16:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	18DEC2019	17:08		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	17OCT2014	16:03	lower	Double Read
					VISIT 3A	08JAN2015	16:00	lower	Double Read
					VISIT 4	19FEB2015	16:08	lower	Double Read
					VISIT 6	01JUL2015	16:06	lower	Double Read
					VISIT 7	13JAN2016	19:16	lower	Double Read
					VISIT 8	11JAN2017	16:14	lower	Double Read
					VISIT 11	18DEC2019	17:08	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	17OCT2014	16:03	8.0686257856	Double Read
					VISIT 3A	08JAN2015	16:00	9.9701783590	Double Read
					VISIT 4	19FEB2015	16:08	11.097897061	Double Read
					VISIT 6	01JUL2015	16:06	9.5869067436	Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14	9.4369899779	Double Read
					VISIT 11	18DEC2019	17:08	8.2328316629	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	17OCT2014	16:03	3.6521148292	Double Read
					VISIT 3A	08JAN2015	16:00	3.2953966366	Double Read
					VISIT 4	19FEB2015	16:08	3.2662748428	Double Read
					VISIT 6	01JUL2015	16:06	3.6294683200	Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14	8.3573976558	Double Read
					VISIT 11	18DEC2019	17:08	4.7926414132	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	17OCT2014	16:03	15910.5	Double Read
					VISIT 3A	08JAN2015	16:00	15608.0	Double Read
					VISIT 4	19FEB2015	16:08	14098.5	Double Read
					VISIT 6	01JUL2015	16:06	15055.5	Double Read
					VISIT 7	13JAN2016	19:16	15495.0	Double Read
					VISIT 8	11JAN2017	16:14	14740.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0127 Age=36 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 11	18DEC2019	17:08	9660.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	17OCT2014	16:03	17094.5	Double Read
					VISIT 3A	08JAN2015	16:00	15857.5	Double Read
					VISIT 4	19FEB2015	16:08	16552.5	Double Read
					VISIT 6	01JUL2015	16:06	18830.0	Double Read
					VISIT 7	13JAN2016	19:16	17088.5	Double Read
					VISIT 8	11JAN2017	16:14	17932.0	Double Read
					VISIT 11	18DEC2019	17:08	17485.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	17OCT2014	16:03		Double Read
					VISIT 3A	08JAN2015	16:00		Double Read
					VISIT 4	19FEB2015	16:08		Double Read
					VISIT 6	01JUL2015	16:06		Double Read
					VISIT 7	13JAN2016	19:16		Double Read
					VISIT 8	11JAN2017	16:14		Double Read
					VISIT 11	18DEC2019	17:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	20OCT2014	16:43	3	Double Read
					VISIT 3A	12JAN2015	16:38	4	Double Read
					VISIT 4	24FEB2015	16:17	4	Double Read
					VISIT 6	21JUL2015	16:08	4	Double Read
					VISIT 7	14JAN2016	16:12	4	Double Read
					VISIT 8	25JAN2017	16:55	4	Double Read
					VISIT 11	18DEC2019	16:15	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	20OCT2014	16:43	3	Double Read
					VISIT 3A	12JAN2015	16:38	3	Double Read
					VISIT 4	24FEB2015	16:17	3	Double Read
					VISIT 6	21JUL2015	16:08	3	Double Read
					VISIT 7	14JAN2016	16:12	3	Double Read
					VISIT 8	25JAN2017	16:55	4	Double Read
					VISIT 11	18DEC2019	16:15	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	20OCT2014	16:43	2	Double Read
					VISIT 3A	12JAN2015	16:38	2	Double Read
					VISIT 4	24FEB2015	16:17	2	Double Read
					VISIT 6	21JUL2015	16:08	2	Double Read
					VISIT 7	14JAN2016	16:12	2	Double Read
					VISIT 8	25JAN2017	16:55	2	Double Read
					VISIT 11	18DEC2019	16:15	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read
					VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	20OCT2014	16:43	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read
					VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read
					VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 11	18DEC2019	16:15	N	Double Read
					Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	Y	Double Read
					VISIT 4	24FEB2015	16:17	Y	Double Read
					VISIT 6	21JUL2015	16:08	Y	Double Read
					VISIT 7	14JAN2016	16:12	Y	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read
					Baseline	20OCT2014	16:43	Y	Double Read
					VISIT 3A	12JAN2015	16:38	Y	Double Read
					VISIT 4	24FEB2015	16:17	Y	Double Read
					VISIT 6	21JUL2015	16:08	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read
					Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read
					VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read
Fracture	4_5		General		Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read
					VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	20OCT2014	16:43	12.905	Double Read
					VISIT 3A	12JAN2015	16:38	15.02	Double Read
					VISIT 4	24FEB2015	16:17	14.65	Double Read
					VISIT 6	21JUL2015	16:08	15.405	Double Read
					VISIT 7	14JAN2016	16:12	15.07	Double Read
					VISIT 8	25JAN2017	16:55	14.925	Double Read
					VISIT 11	18DEC2019	16:15	14.27	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	20OCT2014	16:43	13.11	Double Read
					VISIT 3A	12JAN2015	16:38	12.855	Double Read
					VISIT 4	24FEB2015	16:17	12.62	Double Read
					VISIT 6	21JUL2015	16:08	12.085	Double Read
					VISIT 7	14JAN2016	16:12	10.865	Double Read
					VISIT 8	25JAN2017	16:55	11.82	Double Read
					VISIT 11	18DEC2019	16:15	11.015	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	20OCT2014	16:43	13.48	Double Read
					VISIT 3A	12JAN2015	16:38	13.08	Double Read
					VISIT 4	24FEB2015	16:17	13.495	Double Read
					VISIT 6	21JUL2015	16:08	12.89	Double Read
					VISIT 7	14JAN2016	16:12	12.935	Double Read
					VISIT 8	25JAN2017	16:55	13.325	Double Read
					VISIT 11	18DEC2019	16:15	13.21	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	20OCT2014	16:43	10.30635	Double Read
					VISIT 3A	12JAN2015	16:38	10.15411	Double Read
					VISIT 4	24FEB2015	16:17	9.27605	Double Read
					VISIT 6	21JUL2015	16:08	8.840215	Double Read
					VISIT 7	14JAN2016	16:12	10.8626	Double Read
					VISIT 8	25JAN2017	16:55	10.038835	Double Read
					VISIT 11	18DEC2019	16:15	10.07082	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	20OCT2014	16:43	9.16536	Double Read
					VISIT 3A	12JAN2015	16:38	8.991075	Double Read
					VISIT 4	24FEB2015	16:17	8.402435	Double Read
					VISIT 6	21JUL2015	16:08	7.383175	Double Read
					VISIT 7	14JAN2016	16:12	6.36688	Double Read
					VISIT 8	25JAN2017	16:55	8.236365	Double Read
					VISIT 11	18DEC2019	16:15	8.91871	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	20OCT2014	16:43	11.766	Double Read
					VISIT 3A	12JAN2015	16:38	11.36165	Double Read
					VISIT 4	24FEB2015	16:17	11.8786	Double Read
					VISIT 6	21JUL2015	16:08	11.4902	Double Read
					VISIT 7	14JAN2016	16:12	11.6323	Double Read
					VISIT 8	25JAN2017	16:55	10.4062	Double Read
					VISIT 11	18DEC2019	16:15	11.51455	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read
					VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read
					VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read
					VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read
					VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read
					VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read
					VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read
Normal lordotic LS	4_5		General		Baseline	20OCT2014	16:43	Y	Double Read
					VISIT 3A	12JAN2015	16:38	Y	Double Read
					VISIT 4	24FEB2015	16:17	Y	Double Read
					VISIT 6	21JUL2015	16:08	Y	Double Read
					VISIT 7	14JAN2016	16:12	Y	Double Read
					VISIT 8	25JAN2017	16:55	Y	Double Read
					VISIT 11	18DEC2019	16:15	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	20OCT2014	16:43	0	Double Read
					VISIT 3A	12JAN2015	16:38	0	Double Read
					VISIT 4	24FEB2015	16:17	0	Double Read
					VISIT 6	21JUL2015	16:08	0	Double Read
					VISIT 7	14JAN2016	16:12	0	Double Read
					VISIT 8	25JAN2017	16:55	0	Double Read
					VISIT 11	18DEC2019	16:15	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	20OCT2014	16:43	0	Double Read
					VISIT 3A	12JAN2015	16:38	2	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 4	24FEB2015	16:17	0	Double Read
					VISIT 6	21JUL2015	16:08	1	Double Read
					VISIT 7	14JAN2016	16:12	1	Double Read
					VISIT 8	25JAN2017	16:55	2	Double Read
					VISIT 11	18DEC2019	16:15	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	20OCT2014	16:43	0	Double Read
					VISIT 3A	12JAN2015	16:38	0	Double Read
					VISIT 4	24FEB2015	16:17	0	Double Read
					VISIT 6	21JUL2015	16:08	0	Double Read
					VISIT 7	14JAN2016	16:12	0	Double Read
					VISIT 8	25JAN2017	16:55	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 11	18DEC2019	16:15	0	Double Read
					Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read
					VISIT 7	14JAN2016	16:12	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read
					Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read
					Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read
					VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read
Relevant scoliosis	4_5		General		Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read
					VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read
					VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read
					VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	20OCT2014	16:43	N	Double Read
					VISIT 3A	12JAN2015	16:38	N	Double Read
					VISIT 4	24FEB2015	16:17	N	Double Read
					VISIT 6	21JUL2015	16:08	N	Double Read
					VISIT 7	14JAN2016	16:12	N	Double Read
					VISIT 8	25JAN2017	16:55	N	Double Read
					VISIT 11	18DEC2019	16:15	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	20OCT2014	16:43	67.07376	Double Read
					VISIT 3A	12JAN2015	16:38	68.18	Double Read
					VISIT 4	24FEB2015	16:17	68.55072	Double Read
					VISIT 6	21JUL2015	16:08	68.0856	Double Read
					VISIT 7	14JAN2016	16:12	72.35264	Double Read
					VISIT 8	25JAN2017	16:55	71.48896	Double Read
					VISIT 11	18DEC2019	16:15	61.55968	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	20OCT2014	16:43	78.3448	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	12JAN2015	16:38	85.92432	Double Read
					VISIT 4	24FEB2015	16:17	83.61088	Double Read
					VISIT 6	21JUL2015	16:08	79.09344	Double Read
					VISIT 7	14JAN2016	16:12	73.97184	Double Read
					VISIT 8	25JAN2017	16:55	79.26496	Double Read
					VISIT 11	18DEC2019	16:15	69.72448	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	20OCT2014	16:43	106.7576	Double Read
					VISIT 3A	12JAN2015	16:38	110.6312	Double Read
					VISIT 4	24FEB2015	16:17	118.10624	Double Read
					VISIT 6	21JUL2015	16:08	108.83072	Double Read
					VISIT 7	14JAN2016	16:12	115.3368	Double Read
					VISIT 8	25JAN2017	16:55	112.49584	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	18DEC2019	16:15	112.616	Double Read
					VISIT 3A	12JAN2015	16:38		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	20OCT2014	16:43	equal	Double Read
					VISIT 3A	12JAN2015	16:38	higher	Double Read
					VISIT 4	24FEB2015	16:17	higher	Double Read
					VISIT 6	21JUL2015	16:08	higher	Double Read
					VISIT 7	14JAN2016	16:12	higher	Double Read
					VISIT 8	25JAN2017	16:55	equal	Double Read
					VISIT 11	18DEC2019	16:15	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 8	25JAN2017	16:55		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		VISIT 11	18DEC2019	16:15		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	20OCT2014	16:43	lower	Double Read
					VISIT 3A	12JAN2015	16:38	lower	Double Read
					VISIT 4	24FEB2015	16:17	lower	Double Read
					VISIT 6	21JUL2015	16:08	lower	Double Read
					VISIT 7	14JAN2016	16:12	lower	Double Read
					VISIT 8	25JAN2017	16:55	lower	Double Read
					VISIT 11	18DEC2019	16:15	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	20OCT2014	16:43	6.4872566672	Double Read
					VISIT 3A	12JAN2015	16:38	8.3915882452	Double Read
					VISIT 4	24FEB2015	16:17	9.6942619330	Double Read
					VISIT 6	21JUL2015	16:08	9.9158484796	Double Read
					VISIT 7	14JAN2016	16:12	8.0667640563	Double Read
					VISIT 8	25JAN2017	16:55	10.131285884	Double Read
					VISIT 11	18DEC2019	16:15	6.5312247324	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	20OCT2014	16:43	7.5543060981	Double Read
					VISIT 3A	12JAN2015	16:38	7.8562935281	Double Read
					VISIT 4	24FEB2015	16:17	10.022082554	Double Read
					VISIT 6	21JUL2015	16:08	10.107015457	Double Read
					VISIT 7	14JAN2016	16:12	8.5216035332	Double Read
					VISIT 8	25JAN2017	16:55	9.1808391370	Double Read
					VISIT 11	18DEC2019	16:15	2.1457516562	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	20OCT2014	16:43	2.5107796840	Double Read
					VISIT 3A	12JAN2015	16:38	18.696585697	Double Read
					VISIT 4	24FEB2015	16:17	7.0211109223	Double Read
					VISIT 6	21JUL2015	16:08	3.0915576694	Double Read
					VISIT 7	14JAN2016	16:12	2.6620417869	Double Read
					VISIT 8	25JAN2017	16:55	3.2444368948	Double Read
					VISIT 11	18DEC2019	16:15	12.169940547	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	20OCT2014	16:43		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	20OCT2014	16:43	15857.0	Double Read
					VISIT 3A	12JAN2015	16:38	17558.5	Double Read
					VISIT 4	24FEB2015	16:17	16168.0	Double Read
					VISIT 6	21JUL2015	16:08	16515.0	Double Read
					VISIT 7	14JAN2016	16:12	17345.5	Double Read
					VISIT 8	25JAN2017	16:55	16772.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	VISIT 11	18DEC2019	16:15	15411.0	Double Read
					Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
					Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read
					Baseline	20OCT2014	16:43	13944.5	Double Read
					VISIT 3A	12JAN2015	16:38	14288.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 4	24FEB2015	16:17	14749.0	Double Read
					VISIT 6	21JUL2015	16:08	13434.5	Double Read
					VISIT 7	14JAN2016	16:12	12766.0	Double Read
					VISIT 8	25JAN2017	16:55	13082.0	Double Read
					VISIT 11	18DEC2019	16:15	12669.0	Double Read
Volume (mm ³) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
Volume (mm ³) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read
					VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
Volume (mm ³) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	20OCT2014	16:43	17016.0	Double Read
					VISIT 3A	12JAN2015	16:38	19359.5	Double Read
					VISIT 4	24FEB2015	16:17	17423.0	Double Read
					VISIT 6	21JUL2015	16:08	18046.0	Double Read
					VISIT 7	14JAN2016	16:12	17130.0	Double Read
					VISIT 8	25JAN2017	16:55	17717.0	Double Read
Volume (mm ³) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	18DEC2019	16:15	17764.0	Double Read
					Baseline	20OCT2014	16:43		Double Read
					VISIT 3A	12JAN2015	16:38		Double Read
					VISIT 4	24FEB2015	16:17		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0128 Age=24 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 6	21JUL2015	16:08		Double Read
					VISIT 7	14JAN2016	16:12		Double Read
					VISIT 8	25JAN2017	16:55		Double Read
					VISIT 11	18DEC2019	16:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0129 Age=47 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	28OCT2014	16:08	2	Double Read
					VISIT 4	10DEC2014	16:20	2	Double Read
					VISIT 6	14APR2015	15:56	2	Double Read
					VISIT 7	21OCT2015	16:04	2	Double Read
					VISIT 8	05OCT2016	16:59	2	Double Read
					VISIT 11	02OCT2019	17:05	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	28OCT2014	16:08	2	Double Read
					VISIT 4	10DEC2014	16:20	2	Double Read
					VISIT 6	14APR2015	15:56	3	Double Read
					VISIT 7	21OCT2015	16:04	3	Double Read
					VISIT 8	05OCT2016	16:59	3	Double Read
					VISIT 11	02OCT2019	17:05	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	28OCT2014	16:08	2	Double Read
					VISIT 4	10DEC2014	16:20	2	Double Read
					VISIT 6	14APR2015	15:56	2	Double Read
					VISIT 7	21OCT2015	16:04	2	Double Read
					VISIT 8	05OCT2016	16:59	2	Double Read
					VISIT 11	02OCT2019	17:05	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read
					VISIT 11	02OCT2019	17:05	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0129 Age=47 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 11	02OCT2019	17:05	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read
					VISIT 11	02OCT2019	17:05	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read
					VISIT 11	02OCT2019	17:05	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	28OCT2014	16:08	Y	Double Read
					VISIT 4	10DEC2014	16:20	Y	Double Read
					VISIT 6	14APR2015	15:56	Y	Double Read
					VISIT 7	21OCT2015	16:04	Y	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read
					VISIT 11	02OCT2019	17:05	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read
					VISIT 11	02OCT2019	17:05	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0129 Age=47 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	4_5		General		VISIT 11	02OCT2019	17:05	N	Double Read
Fracture	4_5		General		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read
					VISIT 11	02OCT2019	17:05	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	28OCT2014	16:08	15.615	Double Read
					VISIT 4	10DEC2014	16:20	13.925	Double Read
					VISIT 6	14APR2015	15:56	15.915	Double Read
					VISIT 7	21OCT2015	16:04	14.955	Double Read
					VISIT 8	05OCT2016	16:59	17.085	Double Read
					VISIT 11	02OCT2019	17:05	14.64	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	28OCT2014	16:08	14.695	Double Read
					VISIT 4	10DEC2014	16:20	13.605	Double Read
					VISIT 6	14APR2015	15:56	14.825	Double Read
					VISIT 7	21OCT2015	16:04	13.48	Double Read
					VISIT 8	05OCT2016	16:59	14.735	Double Read
					VISIT 11	02OCT2019	17:05	14.53	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	28OCT2014	16:08	14.285	Double Read
					VISIT 4	10DEC2014	16:20	15.61	Double Read
					VISIT 6	14APR2015	15:56	16.87	Double Read
					VISIT 7	21OCT2015	16:04	15.21	Double Read
					VISIT 8	05OCT2016	16:59	15.78	Double Read
					VISIT 11	02OCT2019	17:05	15.42	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	28OCT2014	16:08	11.96265	Double Read
					VISIT 4	10DEC2014	16:20	11.2965	Double Read
					VISIT 6	14APR2015	15:56	11.27845	Double Read
					VISIT 7	21OCT2015	16:04	11.96465	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0129 Age=47 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	VISIT 8	05OCT2016	16:59	11.8236	Double Read
					VISIT 11	02OCT2019	17:05	11.65405	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	28OCT2014	16:08	12.99485	Double Read
					VISIT 4	10DEC2014	16:20	10.9206	Double Read
					VISIT 6	14APR2015	15:56	12.0554	Double Read
					VISIT 7	21OCT2015	16:04	11.6435	Double Read
					VISIT 8	05OCT2016	16:59	11.5985	Double Read
					VISIT 11	02OCT2019	17:05	12.09945	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	28OCT2014	16:08	13.82255	Double Read
					VISIT 4	10DEC2014	16:20	12.5922	Double Read
					VISIT 6	14APR2015	15:56	12.4489	Double Read
					VISIT 7	21OCT2015	16:04	12.9005	Double Read
					VISIT 8	05OCT2016	16:59	13.92235	Double Read
					VISIT 11	02OCT2019	17:05	13.1424	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read
					VISIT 11	02OCT2019	17:05	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read
					VISIT 11	02OCT2019	17:05	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0129 Age=47 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read
					VISIT 11	02OCT2019	17:05	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read
					VISIT 11	02OCT2019	17:05	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read
					VISIT 11	02OCT2019	17:05	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read
					VISIT 11	02OCT2019	17:05	N	Double Read
Normal lordotic LS	4_5		General		Baseline	28OCT2014	16:08	Y	Double Read
					VISIT 4	10DEC2014	16:20	Y	Double Read
					VISIT 6	14APR2015	15:56	Y	Double Read
					VISIT 7	21OCT2015	16:04	Y	Double Read
					VISIT 8	05OCT2016	16:59	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0129 Age=47 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	4_5		General		VISIT 11	02OCT2019	17:05	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	28OCT2014	16:08	0	Double Read
					VISIT 4	10DEC2014	16:20	0	Double Read
					VISIT 6	14APR2015	15:56	0	Double Read
					VISIT 7	21OCT2015	16:04	0	Double Read
					VISIT 8	05OCT2016	16:59	0	Double Read
					VISIT 11	02OCT2019	17:05	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	28OCT2014	16:08	0	Double Read
					VISIT 4	10DEC2014	16:20	0	Double Read
					VISIT 6	14APR2015	15:56	0	Double Read
					VISIT 7	21OCT2015	16:04	0	Double Read
					VISIT 8	05OCT2016	16:59	0	Double Read
					VISIT 11	02OCT2019	17:05	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	28OCT2014	16:08	0	Double Read
					VISIT 4	10DEC2014	16:20	0	Double Read
					VISIT 6	14APR2015	15:56	0	Double Read
					VISIT 7	21OCT2015	16:04	0	Double Read
					VISIT 8	05OCT2016	16:59	0	Double Read
					VISIT 11	02OCT2019	17:05	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read
					VISIT 11	02OCT2019	17:05	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0129 Age=47 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 11	02OCT2019	17:05	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read
					VISIT 11	02OCT2019	17:05	N	Double Read
Relevant scoliosis	4_5		General		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read
					VISIT 11	02OCT2019	17:05	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read
					VISIT 11	02OCT2019	17:05	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read
					VISIT 8	05OCT2016	16:59	N	Double Read
					VISIT 11	02OCT2019	17:05	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	28OCT2014	16:08	N	Double Read
					VISIT 4	10DEC2014	16:20	N	Double Read
					VISIT 6	14APR2015	15:56	N	Double Read
					VISIT 7	21OCT2015	16:04	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0129 Age=47 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	05OCT2016	16:59	N	Double Read
					VISIT 11	02OCT2019	17:05	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	28OCT2014	16:08	88.86192	Double Read
					VISIT 4	10DEC2014	16:20	90.2768	Double Read
					VISIT 6	14APR2015	15:56	84.89968	Double Read
					VISIT 7	21OCT2015	16:04	85.8056	Double Read
					VISIT 8	05OCT2016	16:59	82.9776	Double Read
					VISIT 11	02OCT2019	17:05	79.56624	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	28OCT2014	16:08	86.4704	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0129 Age=47 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 4	10DEC2014	16:20	89.38224	Double Read
					VISIT 6	14APR2015	15:56	77.50192	Double Read
					VISIT 7	21OCT2015	16:04	87.36832	Double Read
					VISIT 8	05OCT2016	16:59	77.6392	Double Read
					VISIT 11	02OCT2019	17:05	73.048	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	28OCT2014	16:08	85.0176	Double Read
					VISIT 4	10DEC2014	16:20	88.7216	Double Read
					VISIT 6	14APR2015	15:56	84.18224	Double Read
					VISIT 7	21OCT2015	16:04	87.25952	Double Read
					VISIT 8	05OCT2016	16:59	77.86352	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	02OCT2019	17:05	74.98688	Double Read
					Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0129 Age=47 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0129 Age=47 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	28OCT2014	16:08	equal	Double Read
					VISIT 4	10DEC2014	16:20	lower	Double Read
					VISIT 6	14APR2015	15:56	lower	Double Read
					VISIT 7	21OCT2015	16:04	lower	Double Read
					VISIT 8	05OCT2016	16:59	lower	Double Read
					VISIT 11	02OCT2019	17:05	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	28OCT2014	16:08	equal	Double Read
					VISIT 4	10DEC2014	16:20	lower	Double Read
					VISIT 6	14APR2015	15:56	lower	Double Read
					VISIT 7	21OCT2015	16:04	lower	Double Read
					VISIT 8	05OCT2016	16:59	lower	Double Read
					VISIT 11	02OCT2019	17:05	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0129 Age=47 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0129 Age=47 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	28OCT2014	16:08	5.84338372686	Double Read
					VISIT 4	10DEC2014	16:20	10.0301749618	Double Read
					VISIT 6	14APR2015	15:56	6.48132495329	Double Read
					VISIT 7	21OCT2015	16:04	9.39923900119	Double Read
					VISIT 8	05OCT2016	16:59	11.7320672668	Double Read
					VISIT 11	02OCT2019	17:05	11.6641209444	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	28OCT2014	16:08	13.7402547987	Double Read
					VISIT 4	10DEC2014	16:20	2.80036011551	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0129 Age=47 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 6	14APR2015	15:56	12.9037336504	Double Read
					VISIT 7	21OCT2015	16:04	10.2267572618	Double Read
					VISIT 8	05OCT2016	16:59	11.6074944794	Double Read
					VISIT 11	02OCT2019	17:05	12.0335043316	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	28OCT2014	16:08	13.9095634449	Double Read
					VISIT 4	10DEC2014	16:20	8.51756072702	Double Read
					VISIT 6	14APR2015	15:56	14.0233667403	Double Read
					VISIT 7	21OCT2015	16:04	7.2343944284	Double Read
					VISIT 8	05OCT2016	16:59	6.99452352641	Double Read
					VISIT 11	02OCT2019	17:05	8.93265839986	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0129 Age=47 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	28OCT2014	16:08	15299.5	Double Read
					VISIT 4	10DEC2014	16:20	14868.0	Double Read
					VISIT 6	14APR2015	15:56	15836.0	Double Read
					VISIT 7	21OCT2015	16:04	15758.5	Double Read
					VISIT 8	05OCT2016	16:59	17944.0	Double Read
					VISIT 11	02OCT2019	17:05	13840.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0129 Age=47 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	VISIT 11	02OCT2019	17:05		Double Read
Volume (mm ³) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	28OCT2014	16:08	19342.5	Double Read
					VISIT 4	10DEC2014	16:20	18270.0	Double Read
					VISIT 6	14APR2015	15:56	18642.0	Double Read
					VISIT 7	21OCT2015	16:04	18883.5	Double Read
					VISIT 8	05OCT2016	16:59	19794.5	Double Read
					VISIT 11	02OCT2019	17:05	17660.0	Double Read
Volume (mm ³) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
Volume (mm ³) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read
					VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read
Volume (mm ³) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	28OCT2014	16:08	18815.5	Double Read
					VISIT 4	10DEC2014	16:20	20071.5	Double Read
					VISIT 6	14APR2015	15:56	20258.0	Double Read
					VISIT 7	21OCT2015	16:04	20678.0	Double Read
					VISIT 8	05OCT2016	16:59	22349.0	Double Read
					VISIT 11	02OCT2019	17:05	19185.0	Double Read
Volume (mm ³) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	28OCT2014	16:08		Double Read
					VISIT 4	10DEC2014	16:20		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0129 Age=47 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 6	14APR2015	15:56		Double Read
					VISIT 7	21OCT2015	16:04		Double Read
					VISIT 8	05OCT2016	16:59		Double Read
					VISIT 11	02OCT2019	17:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	19NOV2014	18:06	2	Double Read
					VISIT 3A	02FEB2015	16:14	2	Double Read
					VISIT 4	17MAR2015	16:03	2	Double Read
					VISIT 6	29JUL2015	16:23	2	Double Read
					VISIT 7	20JAN2016	15:46	2	Double Read
					VISIT 8	01FEB2017	16:44	2	Double Read
					VISIT 11	22JAN2020	16:51	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	19NOV2014	18:06	4	Double Read
					VISIT 3A	02FEB2015	16:14	4	Double Read
					VISIT 4	17MAR2015	16:03	4	Double Read
					VISIT 6	29JUL2015	16:23	4	Double Read
					VISIT 7	20JAN2016	15:46	4	Double Read
					VISIT 8	01FEB2017	16:44	4	Double Read
					VISIT 11	22JAN2020	16:51	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	19NOV2014	18:06	2	Double Read
					VISIT 3A	02FEB2015	16:14	2	Double Read
					VISIT 4	17MAR2015	16:03	3	Double Read
					VISIT 6	29JUL2015	16:23	2	Double Read
					VISIT 7	20JAN2016	15:46	2	Double Read
					VISIT 8	01FEB2017	16:44	2	Double Read
					VISIT 11	22JAN2020	16:51	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
					VISIT 7	20JAN2016	15:46	N	Double Read
					VISIT 8	01FEB2017	16:44	N	Double Read
					VISIT 11	22JAN2020	16:51	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	19NOV2014	18:06	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
					VISIT 7	20JAN2016	15:46	N	Double Read
					VISIT 8	01FEB2017	16:44	N	Double Read
					VISIT 11	22JAN2020	16:51	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
					VISIT 7	20JAN2016	15:46	N	Double Read
					VISIT 8	01FEB2017	16:44	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 11	22JAN2020	16:51	N	Double Read
					Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
					VISIT 7	20JAN2016	15:46	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		VISIT 8	01FEB2017	16:44	N	Double Read
					VISIT 11	22JAN2020	16:51	N	Double Read
					Baseline	19NOV2014	18:06	Y	Double Read
					VISIT 3A	02FEB2015	16:14	Y	Double Read
					VISIT 4	17MAR2015	16:03	Y	Double Read
					VISIT 6	29JUL2015	16:23	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	20JAN2016	15:46	Y	Double Read
					VISIT 8	01FEB2017	16:44	Y	Double Read
					VISIT 11	22JAN2020	16:51	Y	Double Read
					Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	Y	Double Read
					VISIT 6	29JUL2015	16:23	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	20JAN2016	15:46	N	Double Read
					VISIT 8	01FEB2017	16:44	Y	Double Read
					VISIT 11	22JAN2020	16:51	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
					VISIT 7	20JAN2016	15:46	N	Double Read
					VISIT 8	01FEB2017	16:44	N	Double Read
					VISIT 11	22JAN2020	16:51	N	Double Read
Fracture	4_5		General		Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
					VISIT 7	20JAN2016	15:46	N	Double Read
					VISIT 8	01FEB2017	16:44	N	Double Read
					VISIT 11	22JAN2020	16:51	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	19NOV2014	18:06	14.905	Double Read
					VISIT 3A	02FEB2015	16:14	13.83	Double Read
					VISIT 4	17MAR2015	16:03	14.03	Double Read
					VISIT 6	29JUL2015	16:23	15.35	Double Read
					VISIT 7	20JAN2016	15:46	14.64	Double Read
					VISIT 8	01FEB2017	16:44	15.145	Double Read
					VISIT 11	22JAN2020	16:51	15.205	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	19NOV2014	18:06	12.17	Double Read
					VISIT 3A	02FEB2015	16:14	12.725	Double Read
					VISIT 4	17MAR2015	16:03	14.015	Double Read
					VISIT 6	29JUL2015	16:23	13.92	Double Read
					VISIT 7	20JAN2016	15:46	12.755	Double Read
					VISIT 8	01FEB2017	16:44	10.82	Double Read
					VISIT 11	22JAN2020	16:51	9.51	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	19NOV2014	18:06	11.91	Double Read
					VISIT 3A	02FEB2015	16:14	11.155	Double Read
					VISIT 4	17MAR2015	16:03	11.915	Double Read
					VISIT 6	29JUL2015	16:23	12.425	Double Read
					VISIT 7	20JAN2016	15:46	12.485	Double Read
					VISIT 8	01FEB2017	16:44	11.935	Double Read
					VISIT 11	22JAN2020	16:51	12.135	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	19NOV2014	18:06	10.32015	Double Read
					VISIT 3A	02FEB2015	16:14	10.45015	Double Read
					VISIT 4	17MAR2015	16:03	9.039665	Double Read
					VISIT 6	29JUL2015	16:23	10.32185	Double Read
					VISIT 7	20JAN2016	15:46	10.77015	Double Read
					VISIT 8	01FEB2017	16:44	10.019865	Double Read
					VISIT 11	22JAN2020	16:51	9.83219	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	19NOV2014	18:06	9.14666	Double Read
					VISIT 3A	02FEB2015	16:14	8.129425	Double Read
					VISIT 4	17MAR2015	16:03	7.49751	Double Read
					VISIT 6	29JUL2015	16:23	7.56072	Double Read
					VISIT 7	20JAN2016	15:46	7.60888	Double Read
					VISIT 8	01FEB2017	16:44	6.339285	Double Read
					VISIT 11	22JAN2020	16:51	5.30241	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	19NOV2014	18:06	10.4282	Double Read
					VISIT 3A	02FEB2015	16:14	9.9818	Double Read
					VISIT 4	17MAR2015	16:03	8.832605	Double Read
					VISIT 6	29JUL2015	16:23	10.1242	Double Read
					VISIT 7	20JAN2016	15:46	10.41545	Double Read
					VISIT 8	01FEB2017	16:44	9.247165	Double Read
					VISIT 11	22JAN2020	16:51	9.572665	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
					VISIT 7	20JAN2016	15:46	N	Double Read
					VISIT 8	01FEB2017	16:44	N	Double Read
					VISIT 11	22JAN2020	16:51	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
					VISIT 7	20JAN2016	15:46	N	Double Read
					VISIT 8	01FEB2017	16:44	N	Double Read
					VISIT 11	22JAN2020	16:51	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
					VISIT 7	20JAN2016	15:46	N	Double Read
					VISIT 8	01FEB2017	16:44	N	Double Read
					VISIT 11	22JAN2020	16:51	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
					VISIT 7	20JAN2016	15:46	N	Double Read
					VISIT 8	01FEB2017	16:44	N	Double Read
					VISIT 11	22JAN2020	16:51	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
					VISIT 7	20JAN2016	15:46	N	Double Read
					VISIT 8	01FEB2017	16:44	N	Double Read
					VISIT 11	22JAN2020	16:51	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
					VISIT 7	20JAN2016	15:46	N	Double Read
					VISIT 8	01FEB2017	16:44	N	Double Read
					VISIT 11	22JAN2020	16:51	N	Double Read
Normal lordotic LS	4_5		General		Baseline	19NOV2014	18:06	Y	Double Read
					VISIT 3A	02FEB2015	16:14	Y	Double Read
					VISIT 4	17MAR2015	16:03	Y	Double Read
					VISIT 6	29JUL2015	16:23	Y	Double Read
					VISIT 7	20JAN2016	15:46	Y	Double Read
					VISIT 8	01FEB2017	16:44	Y	Double Read
					VISIT 11	22JAN2020	16:51	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	19NOV2014	18:06	0	Double Read
					VISIT 3A	02FEB2015	16:14	0	Double Read
					VISIT 4	17MAR2015	16:03	2	Double Read
					VISIT 6	29JUL2015	16:23	0	Double Read
					VISIT 7	20JAN2016	15:46	0	Double Read
					VISIT 8	01FEB2017	16:44	2	Double Read
					VISIT 11	22JAN2020	16:51	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	19NOV2014	18:06	2	Double Read
					VISIT 3A	02FEB2015	16:14	2	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 4	17MAR2015	16:03	1	Double Read
					VISIT 6	29JUL2015	16:23	2	Double Read
					VISIT 7	20JAN2016	15:46	0	Double Read
					VISIT 8	01FEB2017	16:44	2	Double Read
					VISIT 11	22JAN2020	16:51	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	19NOV2014	18:06	0	Double Read
					VISIT 3A	02FEB2015	16:14	0	Double Read
					VISIT 4	17MAR2015	16:03	2	Double Read
					VISIT 6	29JUL2015	16:23	0	Double Read
					VISIT 7	20JAN2016	15:46	0	Double Read
					VISIT 8	01FEB2017	16:44	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 11	22JAN2020	16:51	0	Double Read
					Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
					VISIT 7	20JAN2016	15:46	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	01FEB2017	16:44	N	Double Read
					VISIT 11	22JAN2020	16:51	N	Double Read
					Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	20JAN2016	15:46	N	Double Read
					VISIT 8	01FEB2017	16:44	N	Double Read
					VISIT 11	22JAN2020	16:51	Y	Double Read
					Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
					VISIT 7	20JAN2016	15:46	N	Double Read
					VISIT 8	01FEB2017	16:44	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	01FEB2017	16:44	N	Double Read
					VISIT 11	22JAN2020	16:51	N	Double Read
Relevant scoliosis	4_5		General		Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
					VISIT 7	20JAN2016	15:46	N	Double Read
					VISIT 8	01FEB2017	16:44	N	Double Read
					VISIT 11	22JAN2020	16:51	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
					VISIT 7	20JAN2016	15:46	N	Double Read
					VISIT 8	01FEB2017	16:44	N	Double Read
					VISIT 11	22JAN2020	16:51	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
					VISIT 7	20JAN2016	15:46	N	Double Read
					VISIT 8	01FEB2017	16:44	N	Double Read
					VISIT 11	22JAN2020	16:51	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	19NOV2014	18:06	N	Double Read
					VISIT 3A	02FEB2015	16:14	N	Double Read
					VISIT 4	17MAR2015	16:03	N	Double Read
					VISIT 6	29JUL2015	16:23	N	Double Read
					VISIT 7	20JAN2016	15:46	N	Double Read
					VISIT 8	01FEB2017	16:44	N	Double Read
					VISIT 11	22JAN2020	16:51	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	19NOV2014	18:06	92.90656	Double Read
					VISIT 3A	02FEB2015	16:14	97.8168	Double Read
					VISIT 4	17MAR2015	16:03	91.28496	Double Read
					VISIT 6	29JUL2015	16:23	92.95616	Double Read
					VISIT 7	20JAN2016	15:46	92.27232	Double Read
					VISIT 8	01FEB2017	16:44	86.85136	Double Read
					VISIT 11	22JAN2020	16:51	85.43616	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	19NOV2014	18:06	76.76608	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	02FEB2015	16:14	73.26016	Double Read
					VISIT 4	17MAR2015	16:03	73.0176	Double Read
					VISIT 6	29JUL2015	16:23	72.86	Double Read
					VISIT 7	20JAN2016	15:46	76.79168	Double Read
					VISIT 8	01FEB2017	16:44	74.70832	Double Read
					VISIT 11	22JAN2020	16:51	64.95952	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	19NOV2014	18:06	87.71712	Double Read
					VISIT 3A	02FEB2015	16:14	87.78176	Double Read
					VISIT 4	17MAR2015	16:03	83.51824	Double Read
					VISIT 6	29JUL2015	16:23	89.5528	Double Read
					VISIT 7	20JAN2016	15:46	89.50048	Double Read
					VISIT 8	01FEB2017	16:44	91.33904	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	22JAN2020	16:51	89.17712	Double Read
					VISIT 3A	02FEB2015	16:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	19NOV2014	18:06	lower	Double Read
					VISIT 3A	02FEB2015	16:14	lower	Double Read
					VISIT 4	17MAR2015	16:03	lower	Double Read
					VISIT 6	29JUL2015	16:23	lower	Double Read
					VISIT 7	20JAN2016	15:46	lower	Double Read
					VISIT 8	01FEB2017	16:44	lower	Double Read
					VISIT 11	22JAN2020	16:51	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 8	01FEB2017	16:44		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		VISIT 11	22JAN2020	16:51		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	19NOV2014	18:06	lower	Double Read
					VISIT 3A	02FEB2015	16:14	lower	Double Read
					VISIT 4	17MAR2015	16:03	lower	Double Read
					VISIT 6	29JUL2015	16:23	lower	Double Read
					VISIT 7	20JAN2016	15:46	lower	Double Read
					VISIT 8	01FEB2017	16:44	lower	Double Read
					VISIT 11	22JAN2020	16:51	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	19NOV2014	18:06	9.4153898420	Double Read
					VISIT 3A	02FEB2015	16:14	4.0889145575	Double Read
					VISIT 4	17MAR2015	16:03	3.1083200271	Double Read
					VISIT 6	29JUL2015	16:23	5.9679497197	Double Read
					VISIT 7	20JAN2016	15:46	6.5907932733	Double Read
					VISIT 8	01FEB2017	16:44	2.7461661287	Double Read
					VISIT 11	22JAN2020	16:51	5.0390079836	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	19NOV2014	18:06	6.8608119585	Double Read
					VISIT 3A	02FEB2015	16:14	5.0818209614	Double Read
					VISIT 4	17MAR2015	16:03	6.7096993375	Double Read
					VISIT 6	29JUL2015	16:23	6.1906641753	Double Read
					VISIT 7	20JAN2016	15:46	3.5558552743	Double Read
					VISIT 8	01FEB2017	16:44	8.5337319517	Double Read
					VISIT 11	22JAN2020	16:51	7.1909835230	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 11	22JAN2020	16:51		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	19NOV2014	18:06	4.02015967385	Double Read
					VISIT 3A	02FEB2015	16:14	8.7359537965	Double Read
					VISIT 4	17MAR2015	16:03	11.3300492611	Double Read
					VISIT 6	29JUL2015	16:23	5.05242058773	Double Read
					VISIT 7	20JAN2016	15:46	2.31429250891	Double Read
					VISIT 8	01FEB2017	16:44	2.53585187702	Double Read
					VISIT 11	22JAN2020	16:51	2.8136775947	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	19NOV2014	18:06	12085.5	Double Read
					VISIT 3A	02FEB2015	16:14	12251.0	Double Read
					VISIT 4	17MAR2015	16:03	11938.5	Double Read
					VISIT 6	29JUL2015	16:23	12636.0	Double Read
					VISIT 7	20JAN2016	15:46	12492.0	Double Read
					VISIT 8	01FEB2017	16:44	12294.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	VISIT 11	22JAN2020	16:51	11859.0	Double Read
					Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
					Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
					Baseline	19NOV2014	18:06	12246.0	Double Read
					VISIT 3A	02FEB2015	16:14	12786.5	Double Read
					VISIT 4	17MAR2015	16:03	12288.5	Double Read
					VISIT 6	29JUL2015	16:23	12677.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 7	20JAN2016	15:46	13104.5	Double Read
					VISIT 8	01FEB2017	16:44	10608.5	Double Read
					VISIT 11	22JAN2020	16:51	10127.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read
					VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	19NOV2014	18:06	12538.0	Double Read
					VISIT 3A	02FEB2015	16:14	12724.5	Double Read
					VISIT 4	17MAR2015	16:03	13376.0	Double Read
					VISIT 6	29JUL2015	16:23	13877.0	Double Read
					VISIT 7	20JAN2016	15:46	13418.5	Double Read
					VISIT 8	01FEB2017	16:44	12911.0	Double Read
					VISIT 11	22JAN2020	16:51	12825.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	19NOV2014	18:06		Double Read
					VISIT 3A	02FEB2015	16:14		Double Read
					VISIT 4	17MAR2015	16:03		Double Read
					VISIT 6	29JUL2015	16:23		Double Read
					VISIT 7	20JAN2016	15:46		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0130 Age=49 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	01FEB2017	16:44		Double Read
					VISIT 11	22JAN2020	16:51		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	28NOV2014	22:17	3	Double Read
					VISIT 3A	18FEB2015	17:33	3	Double Read
					VISIT 4	09APR2015	15:51	3	Double Read
					VISIT 6	18AUG2015	16:07	3	Double Read
					VISIT 7	18FEB2016	15:56	3	Double Read
					VISIT 8	15MAR2017	16:03	3	Double Read
					VISIT 11	29JAN2020	16:18	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	28NOV2014	22:17	3	Double Read
					VISIT 3A	18FEB2015	17:33	3	Double Read
					VISIT 4	09APR2015	15:51	3	Double Read
					VISIT 6	18AUG2015	16:07	3	Double Read
					VISIT 7	18FEB2016	15:56	3	Double Read
					VISIT 8	15MAR2017	16:03	3	Double Read
					VISIT 11	29JAN2020	16:18	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	28NOV2014	22:17	3	Double Read
					VISIT 3A	18FEB2015	17:33	3	Double Read
					VISIT 4	09APR2015	15:51	3	Double Read
					VISIT 6	18AUG2015	16:07	3	Double Read
					VISIT 7	18FEB2016	15:56	3	Double Read
					VISIT 8	15MAR2017	16:03	4	Double Read
					VISIT 11	29JAN2020	16:18	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
					VISIT 7	18FEB2016	15:56	N	Double Read
					VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	28NOV2014	22:17	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
					VISIT 7	18FEB2016	15:56	N	Double Read
					VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
					VISIT 7	18FEB2016	15:56	N	Double Read
					VISIT 8	15MAR2017	16:03	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 11	29JAN2020	16:18	N	Double Read
					Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
					VISIT 7	18FEB2016	15:56	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read
					Baseline	28NOV2014	22:17	Y	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	18FEB2016	15:56	Y	Double Read
					VISIT 8	15MAR2017	16:03	Y	Double Read
					VISIT 11	29JAN2020	16:18	Y	Double Read
					Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	18FEB2016	15:56	N	Double Read
					VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
					VISIT 7	18FEB2016	15:56	N	Double Read
					VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read
Fracture	4_5		General		Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
					VISIT 7	18FEB2016	15:56	N	Double Read
					VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	28NOV2014	22:17	14.95	Double Read
					VISIT 3A	18FEB2015	17:33	13.605	Double Read
					VISIT 4	09APR2015	15:51	15.39	Double Read
					VISIT 6	18AUG2015	16:07	13.745	Double Read
					VISIT 7	18FEB2016	15:56	14.855	Double Read
					VISIT 8	15MAR2017	16:03	15.68	Double Read
					VISIT 11	29JAN2020	16:18	14.305	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	28NOV2014	22:17	14.15	Double Read
					VISIT 3A	18FEB2015	17:33	15.01	Double Read
					VISIT 4	09APR2015	15:51	13.255	Double Read
					VISIT 6	18AUG2015	16:07	12.375	Double Read
					VISIT 7	18FEB2016	15:56	12.64	Double Read
					VISIT 8	15MAR2017	16:03	13.03	Double Read
					VISIT 11	29JAN2020	16:18	12.155	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	28NOV2014	22:17	12.12	Double Read
					VISIT 3A	18FEB2015	17:33	11.175	Double Read
					VISIT 4	09APR2015	15:51	11.615	Double Read
					VISIT 6	18AUG2015	16:07	10.435	Double Read
					VISIT 7	18FEB2016	15:56	11.375	Double Read
					VISIT 8	15MAR2017	16:03	11.55	Double Read
					VISIT 11	29JAN2020	16:18	11.97	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	28NOV2014	22:17	12.2682	Double Read
					VISIT 3A	18FEB2015	17:33	11.28365	Double Read
					VISIT 4	09APR2015	15:51	12.26695	Double Read
					VISIT 6	18AUG2015	16:07	11.13535	Double Read
					VISIT 7	18FEB2016	15:56	10.65195	Double Read
					VISIT 8	15MAR2017	16:03	11.61735	Double Read
					VISIT 11	29JAN2020	16:18	11.16925	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	28NOV2014	22:17	11.05575	Double Read
					VISIT 3A	18FEB2015	17:33	9.987925	Double Read
					VISIT 4	09APR2015	15:51	10.488425	Double Read
					VISIT 6	18AUG2015	16:07	9.89677	Double Read
					VISIT 7	18FEB2016	15:56	9.16006	Double Read
					VISIT 8	15MAR2017	16:03	9.51818	Double Read
					VISIT 11	29JAN2020	16:18	8.730475	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	28NOV2014	22:17	11.1435	Double Read
					VISIT 3A	18FEB2015	17:33	8.650465	Double Read
					VISIT 4	09APR2015	15:51	10.13765	Double Read
					VISIT 6	18AUG2015	16:07	8.96346	Double Read
					VISIT 7	18FEB2016	15:56	9.276425	Double Read
					VISIT 8	15MAR2017	16:03	9.362295	Double Read
					VISIT 11	29JAN2020	16:18	9.56046	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
					VISIT 7	18FEB2016	15:56	N	Double Read
					VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
					VISIT 7	18FEB2016	15:56	N	Double Read
					VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
					VISIT 7	18FEB2016	15:56	N	Double Read
					VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
					VISIT 7	18FEB2016	15:56	N	Double Read
					VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
					VISIT 7	18FEB2016	15:56	N	Double Read
					VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
					VISIT 7	18FEB2016	15:56	N	Double Read
					VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read
Normal lordotic LS	4_5		General		Baseline	28NOV2014	22:17	Y	Double Read
					VISIT 3A	18FEB2015	17:33	Y	Double Read
					VISIT 4	09APR2015	15:51	Y	Double Read
					VISIT 6	18AUG2015	16:07	Y	Double Read
					VISIT 7	18FEB2016	15:56	Y	Double Read
					VISIT 8	15MAR2017	16:03	Y	Double Read
					VISIT 11	29JAN2020	16:18	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	28NOV2014	22:17	2	Double Read
					VISIT 3A	18FEB2015	17:33	0	Double Read
					VISIT 4	09APR2015	15:51	0	Double Read
					VISIT 6	18AUG2015	16:07	0	Double Read
					VISIT 7	18FEB2016	15:56	0	Double Read
					VISIT 8	15MAR2017	16:03	0	Double Read
					VISIT 11	29JAN2020	16:18	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	28NOV2014	22:17	2	Double Read
					VISIT 3A	18FEB2015	17:33	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 4	09APR2015	15:51	2	Double Read
					VISIT 6	18AUG2015	16:07	0	Double Read
					VISIT 7	18FEB2016	15:56	2	Double Read
					VISIT 8	15MAR2017	16:03	2	Double Read
					VISIT 11	29JAN2020	16:18	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	28NOV2014	22:17	0	Double Read
					VISIT 3A	18FEB2015	17:33	0	Double Read
					VISIT 4	09APR2015	15:51	0	Double Read
					VISIT 6	18AUG2015	16:07	0	Double Read
					VISIT 7	18FEB2016	15:56	0	Double Read
					VISIT 8	15MAR2017	16:03	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 11	29JAN2020	16:18	0	Double Read
					Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
					VISIT 7	18FEB2016	15:56	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read
					Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	18FEB2016	15:56	N	Double Read
					VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read
					Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
					VISIT 7	18FEB2016	15:56	N	Double Read
					VISIT 8	15MAR2017	16:03	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read
Relevant scoliosis	4_5		General		Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
					VISIT 7	18FEB2016	15:56	N	Double Read
					VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
					VISIT 7	18FEB2016	15:56	N	Double Read
					VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
					VISIT 7	18FEB2016	15:56	N	Double Read
					VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	28NOV2014	22:17	N	Double Read
					VISIT 3A	18FEB2015	17:33	N	Double Read
					VISIT 4	09APR2015	15:51	N	Double Read
					VISIT 6	18AUG2015	16:07	N	Double Read
					VISIT 7	18FEB2016	15:56	N	Double Read
					VISIT 8	15MAR2017	16:03	N	Double Read
					VISIT 11	29JAN2020	16:18	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	28NOV2014	22:17	76.77536	Double Read
					VISIT 3A	18FEB2015	17:33	70.79312	Double Read
					VISIT 4	09APR2015	15:51	80.01824	Double Read
					VISIT 6	18AUG2015	16:07	74.6424	Double Read
					VISIT 7	18FEB2016	15:56	76.03264	Double Read
					VISIT 8	15MAR2017	16:03	73.8504	Double Read
					VISIT 11	29JAN2020	16:18	71.1848	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	28NOV2014	22:17	76.2888	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	18FEB2015	17:33	72.7648	Double Read
					VISIT 4	09APR2015	15:51	71.17024	Double Read
					VISIT 6	18AUG2015	16:07	71.29232	Double Read
					VISIT 7	18FEB2016	15:56	75.06416	Double Read
					VISIT 8	15MAR2017	16:03	76.05136	Double Read
					VISIT 11	29JAN2020	16:18	66.56112	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	28NOV2014	22:17	75.9608	Double Read
					VISIT 3A	18FEB2015	17:33	73.78432	Double Read
					VISIT 4	09APR2015	15:51	74.00368	Double Read
					VISIT 6	18AUG2015	16:07	72.59888	Double Read
					VISIT 7	18FEB2016	15:56	77.64176	Double Read
					VISIT 8	15MAR2017	16:03	76.20208	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	29JAN2020	16:18	76.1464	Double Read
					VISIT 3A	18FEB2015	17:33		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	28NOV2014	22:17	equal	Double Read
					VISIT 3A	18FEB2015	17:33	lower	Double Read
					VISIT 4	09APR2015	15:51	equal	Double Read
					VISIT 6	18AUG2015	16:07	lower	Double Read
					VISIT 7	18FEB2016	15:56	equal	Double Read
					VISIT 8	15MAR2017	16:03	equal	Double Read
					VISIT 11	29JAN2020	16:18	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 8	15MAR2017	16:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		VISIT 11	29JAN2020	16:18		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	28NOV2014	22:17	equal	Double Read
					VISIT 3A	18FEB2015	17:33	equal	Double Read
					VISIT 4	09APR2015	15:51	equal	Double Read
					VISIT 6	18AUG2015	16:07	equal	Double Read
					VISIT 7	18FEB2016	15:56	higher	Double Read
					VISIT 8	15MAR2017	16:03	higher	Double Read
					VISIT 11	29JAN2020	16:18	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	28NOV2014	22:17	13.314645829	Double Read
					VISIT 3A	18FEB2015	17:33	9.9485646339	Double Read
					VISIT 4	09APR2015	15:51	12.739935451	Double Read
					VISIT 6	18AUG2015	16:07	10.176510956	Double Read
					VISIT 7	18FEB2016	15:56	13.899847120	Double Read
					VISIT 8	15MAR2017	16:03	11.397995583	Double Read
					VISIT 11	29JAN2020	16:18	8.6631561066	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	28NOV2014	22:17	15.2928146764	Double Read
					VISIT 3A	18FEB2015	17:33	12.5208425344	Double Read
					VISIT 4	09APR2015	15:51	11.0230745711	Double Read
					VISIT 6	18AUG2015	16:07	8.01766604383	Double Read
					VISIT 7	18FEB2016	15:56	10.4184338372	Double Read
					VISIT 8	15MAR2017	16:03	11.0655410226	Double Read
					VISIT 11	29JAN2020	16:18	9.90128758281	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	28NOV2014	22:17	13.249532869	Double Read
					VISIT 3A	18FEB2015	17:33	8.8868150161	Double Read
					VISIT 4	09APR2015	15:51	9.8084593171	Double Read
					VISIT 6	18AUG2015	16:07	8.0629658569	Double Read
					VISIT 7	18FEB2016	15:56	3.7600679463	Double Read
					VISIT 8	15MAR2017	16:03	12.779568540	Double Read
					VISIT 11	29JAN2020	16:18	11.138345507	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	28NOV2014	22:17	14695.5	Double Read
					VISIT 3A	18FEB2015	17:33	12901.5	Double Read
					VISIT 4	09APR2015	15:51	14626.0	Double Read
					VISIT 6	18AUG2015	16:07	12581.0	Double Read
					VISIT 7	18FEB2016	15:56	13729.5	Double Read
					VISIT 8	15MAR2017	16:03	14351.0	Double Read
					VISIT 11	29JAN2020	16:18	13134.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	28NOV2014	22:17	16278.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	18FEB2015	17:33	13931.0	Double Read
					VISIT 4	09APR2015	15:51	14956.5	Double Read
					VISIT 6	18AUG2015	16:07	14605.5	Double Read
					VISIT 7	18FEB2016	15:56	14078.0	Double Read
					VISIT 8	15MAR2017	16:03	15053.0	Double Read
					VISIT 11	29JAN2020	16:18	13818.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read
					VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	28NOV2014	22:17	14183.5	Double Read
					VISIT 3A	18FEB2015	17:33	13277.0	Double Read
					VISIT 4	09APR2015	15:51	13545.5	Double Read
					VISIT 6	18AUG2015	16:07	12518.0	Double Read
					VISIT 7	18FEB2016	15:56	13578.5	Double Read
					VISIT 8	15MAR2017	16:03	14632.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	28NOV2014	22:17		Double Read
					VISIT 3A	18FEB2015	17:33		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0131 Age=32 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	09APR2015	15:51		Double Read
					VISIT 6	18AUG2015	16:07		Double Read
					VISIT 7	18FEB2016	15:56		Double Read
					VISIT 8	15MAR2017	16:03		Double Read
					VISIT 11	29JAN2020	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0132 Age=25 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	01DEC2014	16:30	2	Double Read
					VISIT 4	15JAN2015	15:57	2	Double Read
					VISIT 6	22MAY2015	16:15	2	Double Read
					VISIT 7	25NOV2015	16:42	2	Double Read
					VISIT 8	23NOV2016	17:35	1	Double Read
					VISIT 11	20NOV2019	16:14	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	01DEC2014	16:30	3	Double Read
					VISIT 4	15JAN2015	15:57	3	Double Read
					VISIT 6	22MAY2015	16:15	3	Double Read
					VISIT 7	25NOV2015	16:42	3	Double Read
					VISIT 8	23NOV2016	17:35	3	Double Read
					VISIT 11	20NOV2019	16:14	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01DEC2014	16:30	2	Double Read
					VISIT 4	15JAN2015	15:57	2	Double Read
					VISIT 6	22MAY2015	16:15	2	Double Read
					VISIT 7	25NOV2015	16:42	1	Double Read
					VISIT 8	23NOV2016	17:35	1	Double Read
					VISIT 11	20NOV2019	16:14	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read
					VISIT 11	20NOV2019	16:14	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0132 Age=25 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 11	20NOV2019	16:14	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read
					VISIT 11	20NOV2019	16:14	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read
					VISIT 11	20NOV2019	16:14	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	01DEC2014	16:30	Y	Double Read
					VISIT 4	15JAN2015	15:57	Y	Double Read
					VISIT 6	22MAY2015	16:15	Y	Double Read
					VISIT 7	25NOV2015	16:42	Y	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read
					VISIT 11	20NOV2019	16:14	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read
					VISIT 11	20NOV2019	16:14	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0132 Age=25 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	4_5		General		VISIT 11	20NOV2019	16:14	N	Double Read
Fracture	4_5		General		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read
					VISIT 11	20NOV2019	16:14	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	01DEC2014	16:30	8.415	Double Read
					VISIT 4	15JAN2015	15:57	8.65	Double Read
					VISIT 6	22MAY2015	16:15	8.345	Double Read
					VISIT 7	25NOV2015	16:42	8.06	Double Read
					VISIT 8	23NOV2016	17:35	8.735	Double Read
					VISIT 11	20NOV2019	16:14	8.13	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	01DEC2014	16:30	15.315	Double Read
					VISIT 4	15JAN2015	15:57	17.685	Double Read
					VISIT 6	22MAY2015	16:15	18.145	Double Read
					VISIT 7	25NOV2015	16:42	17.9	Double Read
					VISIT 8	23NOV2016	17:35	18.405	Double Read
					VISIT 11	20NOV2019	16:14	16.305	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	01DEC2014	16:30	16.555	Double Read
					VISIT 4	15JAN2015	15:57	16.395	Double Read
					VISIT 6	22MAY2015	16:15	15.085	Double Read
					VISIT 7	25NOV2015	16:42	15.485	Double Read
					VISIT 8	23NOV2016	17:35	15.875	Double Read
					VISIT 11	20NOV2019	16:14	15.75	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	01DEC2014	16:30	7.37437	Double Read
					VISIT 4	15JAN2015	15:57	6.85505	Double Read
					VISIT 6	22MAY2015	16:15	6.82985	Double Read
					VISIT 7	25NOV2015	16:42	7.28007	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0132 Age=25 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	VISIT 8	23NOV2016	17:35	6.87359	Double Read
					VISIT 11	20NOV2019	16:14	7.066335	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	01DEC2014	16:30	12.312	Double Read
					VISIT 4	15JAN2015	15:57	11.7118	Double Read
					VISIT 6	22MAY2015	16:15	11.7177	Double Read
					VISIT 7	25NOV2015	16:42	12.02965	Double Read
					VISIT 8	23NOV2016	17:35	11.0646	Double Read
					VISIT 11	20NOV2019	16:14	11.6694	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	01DEC2014	16:30	14.00295	Double Read
					VISIT 4	15JAN2015	15:57	14.30035	Double Read
					VISIT 6	22MAY2015	16:15	13.5851	Double Read
					VISIT 7	25NOV2015	16:42	13.7551	Double Read
					VISIT 8	23NOV2016	17:35	13.16625	Double Read
					VISIT 11	20NOV2019	16:14	13.0935	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read
					VISIT 11	20NOV2019	16:14	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read
					VISIT 11	20NOV2019	16:14	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0132 Age=25 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read
					VISIT 11	20NOV2019	16:14	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read
					VISIT 11	20NOV2019	16:14	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read
					VISIT 11	20NOV2019	16:14	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read
					VISIT 11	20NOV2019	16:14	N	Double Read
Normal lordotic LS	4_5		General		Baseline	01DEC2014	16:30	Y	Double Read
					VISIT 4	15JAN2015	15:57	Y	Double Read
					VISIT 6	22MAY2015	16:15	Y	Double Read
					VISIT 7	25NOV2015	16:42	Y	Double Read
					VISIT 8	23NOV2016	17:35	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0132 Age=25 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	4_5		General		VISIT 11	20NOV2019	16:14	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	01DEC2014	16:30	0	Double Read
					VISIT 4	15JAN2015	15:57	0	Double Read
					VISIT 6	22MAY2015	16:15	0	Double Read
					VISIT 7	25NOV2015	16:42	0	Double Read
					VISIT 8	23NOV2016	17:35	0	Double Read
					VISIT 11	20NOV2019	16:14	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	01DEC2014	16:30	0	Double Read
					VISIT 4	15JAN2015	15:57	0	Double Read
					VISIT 6	22MAY2015	16:15	0	Double Read
					VISIT 7	25NOV2015	16:42	0	Double Read
					VISIT 8	23NOV2016	17:35	0	Double Read
					VISIT 11	20NOV2019	16:14	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01DEC2014	16:30	0	Double Read
					VISIT 4	15JAN2015	15:57	0	Double Read
					VISIT 6	22MAY2015	16:15	0	Double Read
					VISIT 7	25NOV2015	16:42	0	Double Read
					VISIT 8	23NOV2016	17:35	0	Double Read
					VISIT 11	20NOV2019	16:14	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read
					VISIT 11	20NOV2019	16:14	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0132 Age=25 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 11	20NOV2019	16:14	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read
					VISIT 11	20NOV2019	16:14	N	Double Read
Relevant scoliosis	4_5		General		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read
					VISIT 11	20NOV2019	16:14	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read
					VISIT 11	20NOV2019	16:14	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read
					VISIT 8	23NOV2016	17:35	N	Double Read
					VISIT 11	20NOV2019	16:14	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01DEC2014	16:30	N	Double Read
					VISIT 4	15JAN2015	15:57	N	Double Read
					VISIT 6	22MAY2015	16:15	N	Double Read
					VISIT 7	25NOV2015	16:42	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0132 Age=25 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	23NOV2016	17:35	N	Double Read
					VISIT 11	20NOV2019	16:14	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	01DEC2014	16:30	95.8328	Double Read
					VISIT 4	15JAN2015	15:57	89.35744	Double Read
					VISIT 6	22MAY2015	16:15	89.70144	Double Read
					VISIT 7	25NOV2015	16:42	94.9808	Double Read
					VISIT 8	23NOV2016	17:35	90.55152	Double Read
					VISIT 11	20NOV2019	16:14	84.096	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	01DEC2014	16:30	77.7248	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0132 Age=25 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 4	15JAN2015	15:57	77.288	Double Read
					VISIT 6	22MAY2015	16:15	67.42544	Double Read
					VISIT 7	25NOV2015	16:42	70.26736	Double Read
					VISIT 8	23NOV2016	17:35	73.71344	Double Read
					VISIT 11	20NOV2019	16:14	64.1128	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	01DEC2014	16:30	108.59552	Double Read
					VISIT 4	15JAN2015	15:57	101.6936	Double Read
					VISIT 6	22MAY2015	16:15	104.02528	Double Read
					VISIT 7	25NOV2015	16:42	106.89632	Double Read
					VISIT 8	23NOV2016	17:35	101.27152	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	20NOV2019	16:14	95.31552	Double Read
					Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0132 Age=25 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0132 Age=25 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	01DEC2014	16:30	lower	Double Read
					VISIT 4	15JAN2015	15:57	lower	Double Read
					VISIT 6	22MAY2015	16:15	lower	Double Read
					VISIT 7	25NOV2015	16:42	lower	Double Read
					VISIT 8	23NOV2016	17:35	lower	Double Read
					VISIT 11	20NOV2019	16:14	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	01DEC2014	16:30	lower	Double Read
					VISIT 4	15JAN2015	15:57	lower	Double Read
					VISIT 6	22MAY2015	16:15	lower	Double Read
					VISIT 7	25NOV2015	16:42	lower	Double Read
					VISIT 8	23NOV2016	17:35	lower	Double Read
					VISIT 11	20NOV2019	16:14	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0132 Age=25 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0132 Age=25 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	01DEC2014	16:30	3.13847460507	Double Read
					VISIT 4	15JAN2015	15:57	2.95404790216	Double Read
					VISIT 6	22MAY2015	16:15	4.756249363	Double Read
					VISIT 7	25NOV2015	16:42	4.77322914897	Double Read
					VISIT 8	23NOV2016	17:35	5.36775947002	Double Read
					VISIT 11	20NOV2019	16:14	7.18289791066	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	01DEC2014	16:30	11.4805028028	Double Read
					VISIT 4	15JAN2015	15:57	10.2485680312	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0132 Age=25 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 6	22MAY2015	16:15	9.07803635128	Double Read
					VISIT 7	25NOV2015	16:42	10.5815593681	Double Read
					VISIT 8	23NOV2016	17:35	11.7782232037	Double Read
					VISIT 11	20NOV2019	16:14	6.52850687957	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	01DEC2014	16:30	7.3013962969	Double Read
					VISIT 4	15JAN2015	15:57	2.23306947512	Double Read
					VISIT 6	22MAY2015	16:15	6.84224902328	Double Read
					VISIT 7	25NOV2015	16:42	5.78109733311	Double Read
					VISIT 8	23NOV2016	17:35	4.63864107355	Double Read
					VISIT 11	20NOV2019	16:14	3.7092508918	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0132 Age=25 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	01DEC2014	16:30	7201.5	Double Read
					VISIT 4	15JAN2015	15:57	7910.0	Double Read
					VISIT 6	22MAY2015	16:15	7253.0	Double Read
					VISIT 7	25NOV2015	16:42	7049.5	Double Read
					VISIT 8	23NOV2016	17:35	7880.0	Double Read
					VISIT 11	20NOV2019	16:14	7289.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0132 Age=25 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	VISIT 11	20NOV2019	16:14		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	01DEC2014	16:30	18002.5	Double Read
					VISIT 4	15JAN2015	15:57	18810.0	Double Read
					VISIT 6	22MAY2015	16:15	18339.0	Double Read
					VISIT 7	25NOV2015	16:42	18607.5	Double Read
					VISIT 8	23NOV2016	17:35	19514.5	Double Read
					VISIT 11	20NOV2019	16:14	16607.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read
					VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	01DEC2014	16:30	21621.5	Double Read
					VISIT 4	15JAN2015	15:57	24216.0	Double Read
					VISIT 6	22MAY2015	16:15	22672.5	Double Read
					VISIT 7	25NOV2015	16:42	22009.0	Double Read
					VISIT 8	23NOV2016	17:35	21012.5	Double Read
					VISIT 11	20NOV2019	16:14	21491.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	01DEC2014	16:30		Double Read
					VISIT 4	15JAN2015	15:57		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0132 Age=25 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 6	22MAY2015	16:15		Double Read
					VISIT 7	25NOV2015	16:42		Double Read
					VISIT 8	23NOV2016	17:35		Double Read
					VISIT 11	20NOV2019	16:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0133 Age=52 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	15DEC2014	15:51	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	15DEC2014	15:51	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	15DEC2014	15:51	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	15DEC2014	15:51	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	15DEC2014	15:51	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	15DEC2014	15:51	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	15DEC2014	15:51	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	15DEC2014	15:51	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	15DEC2014	15:51	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	15DEC2014	15:51	N	Double Read
Fracture	4_5		General		Baseline	15DEC2014	15:51	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	15DEC2014	15:51		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	15DEC2014	15:51		Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	15DEC2014	15:51		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0133 Age=52 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	15DEC2014	15:51		Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	15DEC2014	15:51		Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	15DEC2014	15:51		Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	15DEC2014	15:51	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	15DEC2014	15:51	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	15DEC2014	15:51	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	15DEC2014	15:51	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	15DEC2014	15:51	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	15DEC2014	15:51	N	Double Read
Normal lordotic LS	4_5		General		Baseline	15DEC2014	15:51	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	15DEC2014	15:51	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	15DEC2014	15:51	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0133 Age=52 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	15DEC2014	15:51	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	15DEC2014	15:51	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	15DEC2014	15:51	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	15DEC2014	15:51	N	Double Read
Relevant scoliosis	4_5		General		Baseline	15DEC2014	15:51	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	15DEC2014	15:51	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	15DEC2014	15:51	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	15DEC2014	15:51	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	15DEC2014	15:51		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	15DEC2014	15:51		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	15DEC2014	15:51		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	15DEC2014	15:51		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	15DEC2014	15:51		Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	15DEC2014	15:51		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0133 Age=52 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15DEC2014	15:51		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	15DEC2014	15:51		Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	15DEC2014	15:51		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	15DEC2014	15:51		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	15DEC2014	15:51		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	15DEC2014	15:51		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	15DEC2014	15:51		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	15DEC2014	15:51	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	15DEC2014	15:51		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	15DEC2014	15:51		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0133 Age=52 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	15DEC2014	15:51	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	15DEC2014	15:51		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	15DEC2014	15:51		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	15DEC2014	15:51		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	15DEC2014	15:51		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	15DEC2014	15:51		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	15DEC2014	15:51		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	15DEC2014	15:51		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	15DEC2014	15:51		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	15DEC2014	15:51		Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	15DEC2014	15:51		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15DEC2014	15:51		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0133 Age=52 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	15DEC2014	15:51		Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	15DEC2014	15:51		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	15DEC2014	15:51		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	15DEC2014	15:51		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	15DEC2014	15:51		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	15DEC2014	15:51		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	15DEC2014	15:51		Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	15DEC2014	15:51		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15DEC2014	15:51		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	15DEC2014	15:51		Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	15DEC2014	15:51		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0134 Age=29 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	16DEC2014	16:17		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	16DEC2014	16:17	2	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16DEC2014	16:17	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	16DEC2014	16:17		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	16DEC2014	16:17	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16DEC2014	16:17	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	16DEC2014	16:17		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	16DEC2014	16:17	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16DEC2014	16:17	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	16DEC2014	16:17	N	Double Read
Fracture	5_S		General		Baseline	16DEC2014	16:17	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	16DEC2014	16:17		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16DEC2014	16:17	15.99	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16DEC2014	16:17	12.865	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0134 Age=29 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	16DEC2014	16:17		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16DEC2014	16:17	7.73755	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16DEC2014	16:17	8.141885	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	16DEC2014	16:17		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	16DEC2014	16:17	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16DEC2014	16:17	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	16DEC2014	16:17		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	16DEC2014	16:17	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16DEC2014	16:17	N	Double Read
Normal lordotic LS	5_S		General		Baseline	16DEC2014	16:17	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	16DEC2014	16:17		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	16DEC2014	16:17	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0134 Age=29 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16DEC2014	16:17	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	16DEC2014	16:17		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	16DEC2014	16:17	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16DEC2014	16:17	N	Double Read
Relevant scoliosis	5_S		General		Baseline	16DEC2014	16:17	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	16DEC2014	16:17		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	16DEC2014	16:17	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16DEC2014	16:17	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	16DEC2014	16:17		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	16DEC2014	16:17		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	16DEC2014	16:17		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	16DEC2014	16:17		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16DEC2014	16:17		Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	16DEC2014	16:17		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0134 Age=29 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	16DEC2014	16:17		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16DEC2014	16:17		Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	16DEC2014	16:17		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	16DEC2014	16:17		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	16DEC2014	16:17		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	16DEC2014	16:17		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	16DEC2014	16:17		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	16DEC2014	16:17		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	16DEC2014	16:17		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	16DEC2014	16:17		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0134 Age=29 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	16DEC2014	16:17	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	16DEC2014	16:17		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	16DEC2014	16:17		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	16DEC2014	16:17		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	16DEC2014	16:17		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	16DEC2014	16:17		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	16DEC2014	16:17		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	16DEC2014	16:17		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	16DEC2014	16:17		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16DEC2014	16:17		Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	16DEC2014	16:17		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	16DEC2014	16:17		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0134 Age=29 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16DEC2014	16:17		Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	16DEC2014	16:17		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	16DEC2014	16:17		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	16DEC2014	16:17		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	16DEC2014	16:17		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	16DEC2014	16:17		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16DEC2014	16:17	27294.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	16DEC2014	16:17		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	16DEC2014	16:17		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16DEC2014	16:17	26960.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	16DEC2014	16:17		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	14JAN2015	18:03	4	Double Read
					VISIT 3A	07APR2015	16:17	4	Double Read
					VISIT 4	26MAY2015	16:05	4	Double Read
					VISIT 6	06OCT2015	16:03	4	Double Read
					VISIT 7	06APR2016	16:49	4	Double Read
					VISIT 8	03MAY2017	16:10	4	Double Read
					VISIT 11	27MAY2020	16:22	5	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JAN2015	18:03	2	Double Read
					VISIT 3A	07APR2015	16:17	2	Double Read
					VISIT 4	26MAY2015	16:05	2	Double Read
					VISIT 6	06OCT2015	16:03	2	Double Read
					VISIT 7	06APR2016	16:49	2	Double Read
					VISIT 8	03MAY2017	16:10	2	Double Read
					VISIT 11	27MAY2020	16:22	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	14JAN2015	18:03	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	07APR2015	16:17	N	Double Read
					VISIT 4	26MAY2015	16:05	N	Double Read
					VISIT 6	06OCT2015	16:03	N	Double Read
					VISIT 7	06APR2016	16:49	N	Double Read
					VISIT 8	03MAY2017	16:10	N	Double Read
					VISIT 11	27MAY2020	16:22	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JAN2015	18:03	N	Double Read
					VISIT 3A	07APR2015	16:17	N	Double Read
					VISIT 4	26MAY2015	16:05	N	Double Read
					VISIT 6	06OCT2015	16:03	N	Double Read
					VISIT 7	06APR2016	16:49	N	Double Read
					VISIT 8	03MAY2017	16:10	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	27MAY2020	16:22	N	Double Read
					Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
					Baseline	14JAN2015	18:03	Y	Double Read
					VISIT 3A	07APR2015	16:17	N	Double Read
					VISIT 4	26MAY2015	16:05	Y	Double Read
					VISIT 6	06OCT2015	16:03	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	06APR2016	16:49	N	Double Read
					VISIT 8	03MAY2017	16:10	Y	Double Read
					VISIT 11	27MAY2020	16:22	Y	Double Read
					Baseline	14JAN2015	18:03	N	Double Read
					VISIT 3A	07APR2015	16:17	N	Double Read
					VISIT 4	26MAY2015	16:05	N	Double Read
					VISIT 6	06OCT2015	16:03	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	06APR2016	16:49	N	Double Read
					VISIT 8	03MAY2017	16:10	N	Double Read
					VISIT 11	27MAY2020	16:22	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	14JAN2015	18:03	N	Double Read
					VISIT 3A	07APR2015	16:17	N	Double Read
					VISIT 4	26MAY2015	16:05	N	Double Read
					VISIT 6	06OCT2015	16:03	N	Double Read
					VISIT 7	06APR2016	16:49	N	Double Read
					VISIT 8	03MAY2017	16:10	N	Double Read
					VISIT 11	27MAY2020	16:22	N	Double Read
Fracture	5_S		General		Baseline	14JAN2015	18:03	N	Double Read
					VISIT 3A	07APR2015	16:17	N	Double Read
					VISIT 4	26MAY2015	16:05	N	Double Read
					VISIT 6	06OCT2015	16:03	N	Double Read
					VISIT 7	06APR2016	16:49	N	Double Read
					VISIT 8	03MAY2017	16:10	N	Double Read
					VISIT 11	27MAY2020	16:22	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JAN2015	18:03	16.535	Double Read
					VISIT 3A	07APR2015	16:17	13.04	Double Read
					VISIT 4	26MAY2015	16:05	12.19	Double Read
					VISIT 6	06OCT2015	16:03	12.38	Double Read
					VISIT 7	06APR2016	16:49	13.9	Double Read
					VISIT 8	03MAY2017	16:10	14.23	Double Read
					VISIT 11	27MAY2020	16:22	10.85	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JAN2015	18:03	16.155	Double Read
					VISIT 3A	07APR2015	16:17	14.455	Double Read
					VISIT 4	26MAY2015	16:05	15.25	Double Read
					VISIT 6	06OCT2015	16:03	15.535	Double Read
					VISIT 7	06APR2016	16:49	14.55	Double Read
					VISIT 8	03MAY2017	16:10	16.42	Double Read
					VISIT 11	27MAY2020	16:22	14.545	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JAN2015	18:03	6.076115	Double Read
					VISIT 3A	07APR2015	16:17	6.113905	Double Read
					VISIT 4	26MAY2015	16:05	5.37755	Double Read
					VISIT 6	06OCT2015	16:03	6.323095	Double Read
					VISIT 7	06APR2016	16:49	5.766935	Double Read
					VISIT 8	03MAY2017	16:10	5.62601	Double Read
					VISIT 11	27MAY2020	16:22	4.07359	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JAN2015	18:03	11.37375	Double Read
					VISIT 3A	07APR2015	16:17	11.41285	Double Read
					VISIT 4	26MAY2015	16:05	11.59915	Double Read
					VISIT 6	06OCT2015	16:03	11.70495	Double Read
					VISIT 7	06APR2016	16:49	11.72275	Double Read
					VISIT 8	03MAY2017	16:10	10.54451	Double Read
					VISIT 11	27MAY2020	16:22	11.81785	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	14JAN2015	18:03	N	Double Read
					VISIT 3A	07APR2015	16:17	N	Double Read
					VISIT 4	26MAY2015	16:05	N	Double Read
					VISIT 6	06OCT2015	16:03	N	Double Read
					VISIT 7	06APR2016	16:49	N	Double Read
					VISIT 8	03MAY2017	16:10	N	Double Read
					VISIT 11	27MAY2020	16:22	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JAN2015	18:03	N	Double Read
					VISIT 3A	07APR2015	16:17	N	Double Read
					VISIT 4	26MAY2015	16:05	N	Double Read
					VISIT 6	06OCT2015	16:03	N	Double Read
					VISIT 7	06APR2016	16:49	N	Double Read
					VISIT 8	03MAY2017	16:10	N	Double Read
					VISIT 11	27MAY2020	16:22	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	14JAN2015	18:03	N	Double Read
					VISIT 3A	07APR2015	16:17	N	Double Read
					VISIT 4	26MAY2015	16:05	N	Double Read
					VISIT 6	06OCT2015	16:03	N	Double Read
					VISIT 7	06APR2016	16:49	N	Double Read
					VISIT 8	03MAY2017	16:10	N	Double Read
					VISIT 11	27MAY2020	16:22	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JAN2015	18:03	N	Double Read
					VISIT 3A	07APR2015	16:17	N	Double Read
					VISIT 4	26MAY2015	16:05	N	Double Read
					VISIT 6	06OCT2015	16:03	N	Double Read
					VISIT 7	06APR2016	16:49	N	Double Read
					VISIT 8	03MAY2017	16:10	N	Double Read
					VISIT 11	27MAY2020	16:22	N	Double Read
Normal lordotic LS	5_S		General		Baseline	14JAN2015	18:03	Y	Double Read
					VISIT 3A	07APR2015	16:17	Y	Double Read
					VISIT 4	26MAY2015	16:05	Y	Double Read
					VISIT 6	06OCT2015	16:03	Y	Double Read
					VISIT 7	06APR2016	16:49	Y	Double Read
					VISIT 8	03MAY2017	16:10	Y	Double Read
					VISIT 11	27MAY2020	16:22	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	14JAN2015	18:03	0	Double Read
					VISIT 3A	07APR2015	16:17	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	26MAY2015	16:05	0	Double Read
					VISIT 6	06OCT2015	16:03	0	Double Read
					VISIT 7	06APR2016	16:49	0	Double Read
					VISIT 8	03MAY2017	16:10	0	Double Read
					VISIT 11	27MAY2020	16:22	1	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JAN2015	18:03	0	Double Read
					VISIT 3A	07APR2015	16:17	0	Double Read
					VISIT 4	26MAY2015	16:05	0	Double Read
					VISIT 6	06OCT2015	16:03	0	Double Read
					VISIT 7	06APR2016	16:49	0	Double Read
					VISIT 8	03MAY2017	16:10	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 11	27MAY2020	16:22	0	Double Read
					Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
					Baseline	14JAN2015	18:03	N	Double Read
					VISIT 3A	07APR2015	16:17	N	Double Read
					VISIT 4	26MAY2015	16:05	N	Double Read
					VISIT 6	06OCT2015	16:03	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	06APR2016	16:49	N	Double Read
					VISIT 8	03MAY2017	16:10	N	Double Read
					VISIT 11	27MAY2020	16:22	N	Double Read
					Baseline	14JAN2015	18:03	N	Double Read
					VISIT 3A	07APR2015	16:17	N	Double Read
					VISIT 4	26MAY2015	16:05	N	Double Read
					VISIT 6	06OCT2015	16:03	N	Double Read
					VISIT 7	06APR2016	16:49	N	Double Read
					VISIT 8	03MAY2017	16:10	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	03MAY2017	16:10	N	Double Read
					VISIT 11	27MAY2020	16:22	N	Double Read
Relevant scoliosis	5_S		General		Baseline	14JAN2015	18:03	N	Double Read
					VISIT 3A	07APR2015	16:17	N	Double Read
					VISIT 4	26MAY2015	16:05	N	Double Read
					VISIT 6	06OCT2015	16:03	N	Double Read
					VISIT 7	06APR2016	16:49	N	Double Read
					VISIT 8	03MAY2017	16:10	N	Double Read
					VISIT 11	27MAY2020	16:22	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	14JAN2015	18:03	N	Double Read
					VISIT 3A	07APR2015	16:17	N	Double Read
					VISIT 4	26MAY2015	16:05	N	Double Read
					VISIT 6	06OCT2015	16:03	N	Double Read
					VISIT 7	06APR2016	16:49	N	Double Read
					VISIT 8	03MAY2017	16:10	N	Double Read
					VISIT 11	27MAY2020	16:22	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JAN2015	18:03	N	Double Read
					VISIT 3A	07APR2015	16:17	N	Double Read
					VISIT 4	26MAY2015	16:05	N	Double Read
					VISIT 6	06OCT2015	16:03	N	Double Read
					VISIT 7	06APR2016	16:49	N	Double Read
					VISIT 8	03MAY2017	16:10	N	Double Read
					VISIT 11	27MAY2020	16:22	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JAN2015	18:03	69.62912	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	07APR2015	16:17	71.85568	Double Read
					VISIT 4	26MAY2015	16:05	69.46048	Double Read
					VISIT 6	06OCT2015	16:03	69.48592	Double Read
					VISIT 7	06APR2016	16:49	73.94912	Double Read
					VISIT 8	03MAY2017	16:10	76.31408	Double Read
					VISIT 11	27MAY2020	16:22	71.29488	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JAN2015	18:03	84.92896	Double Read
					VISIT 3A	07APR2015	16:17	86.8224	Double Read
					VISIT 4	26MAY2015	16:05	88.06656	Double Read
					VISIT 6	06OCT2015	16:03	81.18496	Double Read
					VISIT 7	06APR2016	16:49	81.89792	Double Read
					VISIT 8	03MAY2017	16:10	78.59024	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	27MAY2020	16:22	67.92272	Double Read
					Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 8	03MAY2017	16:10		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	27MAY2020	16:22		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	14JAN2015	18:03	lower	Double Read
					VISIT 3A	07APR2015	16:17	lower	Double Read
					VISIT 4	26MAY2015	16:05	lower	Double Read
					VISIT 6	06OCT2015	16:03	lower	Double Read
					VISIT 7	06APR2016	16:49	lower	Double Read
					VISIT 8	03MAY2017	16:10	lower	Double Read
					VISIT 11	27MAY2020	16:22	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JAN2015	18:03	7.6051367419	Double Read
					VISIT 3A	07APR2015	16:17	8 4.6722405299	Double Read
					VISIT 4	26MAY2015	16:05	9 8.0221097333	Double Read
					VISIT 6	06OCT2015	16:03	1 7.0607576015	Double Read
					VISIT 7	06APR2016	16:49	5 5.4604110752	Double Read
					VISIT 8	03MAY2017	16:10	6 6.5681467640	Double Read
					VISIT 11	27MAY2020	16:22	6 11.635807712	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	VISIT 11	27MAY2020	16:22		Double Read
					Baseline	14JAN2015	18:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JAN2015	18:03	5.36237132666	Double Read
					VISIT 3A	07APR2015	16:17	4.92125700696	Double Read
					VISIT 4	26MAY2015	16:05	5.83205707491	Double Read
					VISIT 6	06OCT2015	16:03	8.81415321897	Double Read
					VISIT 7	06APR2016	16:49	8.84245965687	Double Read
					VISIT 8	03MAY2017	16:10	5.92316629862	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
Volume (mm ³) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
Volume (mm ³) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
Volume (mm ³) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
Volume (mm ³) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JAN2015	18:03	9706.5	Double Read
					VISIT 3A	07APR2015	16:17	9803.0	Double Read
					VISIT 4	26MAY2015	16:05	9212.5	Double Read
					VISIT 6	06OCT2015	16:03	9149.0	Double Read
					VISIT 7	06APR2016	16:49	9945.5	Double Read
					VISIT 8	03MAY2017	16:10	10627.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0135 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 11	27MAY2020	16:22	11093.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JAN2015	18:03	16244.5	Double Read
					VISIT 3A	07APR2015	16:17	15310.0	Double Read
					VISIT 4	26MAY2015	16:05	14291.0	Double Read
					VISIT 6	06OCT2015	16:03	14480.5	Double Read
					VISIT 7	06APR2016	16:49	14941.0	Double Read
					VISIT 8	03MAY2017	16:10	15079.5	Double Read
					VISIT 11	27MAY2020	16:22	14675.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	14JAN2015	18:03		Double Read
					VISIT 3A	07APR2015	16:17		Double Read
					VISIT 4	26MAY2015	16:05		Double Read
					VISIT 6	06OCT2015	16:03		Double Read
					VISIT 7	06APR2016	16:49		Double Read
					VISIT 8	03MAY2017	16:10		Double Read
					VISIT 11	27MAY2020	16:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	20FEB2015	16:09	2	Double Read
					VISIT 3A	01JUN2015	15:53	2	Double Read
					VISIT 4	15JUL2015	16:22	2	Double Read
					VISIT 6	24NOV2015	16:42	2	Double Read
					VISIT 7	25MAY2016	16:07	3	Double Read
					VISIT 8	06JUN2017	16:37	2	Double Read
					VISIT 11	10JUN2020	16:09	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	20FEB2015	16:09	3	Double Read
					VISIT 3A	01JUN2015	15:53	3	Double Read
					VISIT 4	15JUL2015	16:22	3	Double Read
					VISIT 6	24NOV2015	16:42	3	Double Read
					VISIT 7	25MAY2016	16:07	4	Double Read
					VISIT 8	06JUN2017	16:37	4	Double Read
					VISIT 11	10JUN2020	16:09	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	20FEB2015	16:09	4	Double Read
					VISIT 3A	01JUN2015	15:53	3	Double Read
					VISIT 4	15JUL2015	16:22	3	Double Read
					VISIT 6	24NOV2015	16:42	3	Double Read
					VISIT 7	25MAY2016	16:07	4	Double Read
					VISIT 8	06JUN2017	16:37	3	Double Read
					VISIT 11	10JUN2020	16:09	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	20FEB2015	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read
					VISIT 7	25MAY2016	16:07	N	Double Read
					VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	20FEB2015	16:09	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read
					VISIT 7	25MAY2016	16:07	N	Double Read
					VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	20FEB2015	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read
					VISIT 7	25MAY2016	16:07	N	Double Read
					VISIT 8	06JUN2017	16:37	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 11	10JUN2020	16:09	N	Double Read
					Baseline	20FEB2015	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read
					VISIT 7	25MAY2016	16:07	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read
					Baseline	20FEB2015	16:09	Y	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	25MAY2016	16:07	Y	Double Read
					VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	Y	Double Read
					Baseline	20FEB2015	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	25MAY2016	16:07	N	Double Read
					VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	20FEB2015	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read
					VISIT 7	25MAY2016	16:07	N	Double Read
					VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read
Fracture	4_5		General		Baseline	20FEB2015	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read
					VISIT 7	25MAY2016	16:07	N	Double Read
					VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	20FEB2015	16:09	18.94	Double Read
					VISIT 3A	01JUN2015	15:53	17.5	Double Read
					VISIT 4	15JUL2015	16:22	17.365	Double Read
					VISIT 6	24NOV2015	16:42	17.375	Double Read
					VISIT 7	25MAY2016	16:07	17.22	Double Read
					VISIT 8	06JUN2017	16:37	18.295	Double Read
					VISIT 11	10JUN2020	16:09	16.2	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	20FEB2015	16:09	12.45	Double Read
					VISIT 3A	01JUN2015	15:53	12.91	Double Read
					VISIT 4	15JUL2015	16:22	12.605	Double Read
					VISIT 6	24NOV2015	16:42	10.845	Double Read
					VISIT 7	25MAY2016	16:07	12.6	Double Read
					VISIT 8	06JUN2017	16:37	13.845	Double Read
					VISIT 11	10JUN2020	16:09	11.935	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	20FEB2015	16:09	15.155	Double Read
					VISIT 3A	01JUN2015	15:53	15.8	Double Read
					VISIT 4	15JUL2015	16:22	13.995	Double Read
					VISIT 6	24NOV2015	16:42	14.665	Double Read
					VISIT 7	25MAY2016	16:07	14.11	Double Read
					VISIT 8	06JUN2017	16:37	14.83	Double Read
					VISIT 11	10JUN2020	16:09	14.29	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	20FEB2015	16:09	13.27035	Double Read
					VISIT 3A	01JUN2015	15:53	13.17855	Double Read
					VISIT 4	15JUL2015	16:22	12.0156	Double Read
					VISIT 6	24NOV2015	16:42	11.67235	Double Read
					VISIT 7	25MAY2016	16:07	11.88315	Double Read
					VISIT 8	06JUN2017	16:37	13.5197	Double Read
					VISIT 11	10JUN2020	16:09	12.9075	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	20FEB2015	16:09	11.1799	Double Read
					VISIT 3A	01JUN2015	15:53	9.34321	Double Read
					VISIT 4	15JUL2015	16:22	9.65697	Double Read
					VISIT 6	24NOV2015	16:42	7.22463	Double Read
					VISIT 7	25MAY2016	16:07	8.822255	Double Read
					VISIT 8	06JUN2017	16:37	7.677975	Double Read
					VISIT 11	10JUN2020	16:09	6.2146	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	20FEB2015	16:09	12.76135	Double Read
					VISIT 3A	01JUN2015	15:53	12.64715	Double Read
					VISIT 4	15JUL2015	16:22	11.8863	Double Read
					VISIT 6	24NOV2015	16:42	10.554635	Double Read
					VISIT 7	25MAY2016	16:07	10.55755	Double Read
					VISIT 8	06JUN2017	16:37	11.87005	Double Read
					VISIT 11	10JUN2020	16:09	12.1263	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	20FEB2015	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read
					VISIT 7	25MAY2016	16:07	N	Double Read
					VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	20FEB2015	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read
					VISIT 7	25MAY2016	16:07	N	Double Read
					VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	20FEB2015	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read
					VISIT 7	25MAY2016	16:07	N	Double Read
					VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	20FEB2015	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read
					VISIT 7	25MAY2016	16:07	N	Double Read
					VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	20FEB2015	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read
					VISIT 7	25MAY2016	16:07	N	Double Read
					VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	20FEB2015	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read
					VISIT 7	25MAY2016	16:07	N	Double Read
					VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read
Normal lordotic LS	4_5		General		Baseline	20FEB2015	16:09	Y	Double Read
					VISIT 3A	01JUN2015	15:53	Y	Double Read
					VISIT 4	15JUL2015	16:22	Y	Double Read
					VISIT 6	24NOV2015	16:42	Y	Double Read
					VISIT 7	25MAY2016	16:07	Y	Double Read
					VISIT 8	06JUN2017	16:37	Y	Double Read
					VISIT 11	10JUN2020	16:09	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	20FEB2015	16:09	0	Double Read
					VISIT 3A	01JUN2015	15:53	0	Double Read
					VISIT 4	15JUL2015	16:22	0	Double Read
					VISIT 6	24NOV2015	16:42	0	Double Read
					VISIT 7	25MAY2016	16:07	0	Double Read
					VISIT 8	06JUN2017	16:37	0	Double Read
					VISIT 11	10JUN2020	16:09	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	20FEB2015	16:09	1	Double Read
					VISIT 3A	01JUN2015	15:53	2	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 4	15JUL2015	16:22	1	Double Read
					VISIT 6	24NOV2015	16:42	1	Double Read
					VISIT 7	25MAY2016	16:07	0	Double Read
					VISIT 8	06JUN2017	16:37	1	Double Read
					VISIT 11	10JUN2020	16:09	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	20FEB2015	16:09	0	Double Read
					VISIT 3A	01JUN2015	15:53	0	Double Read
					VISIT 4	15JUL2015	16:22	0	Double Read
					VISIT 6	24NOV2015	16:42	0	Double Read
					VISIT 7	25MAY2016	16:07	0	Double Read
					VISIT 8	06JUN2017	16:37	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 11	10JUN2020	16:09	0	Double Read
					Baseline	20FEB2015	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read
					VISIT 7	25MAY2016	16:07	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read
					Baseline	20FEB2015	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	25MAY2016	16:07	N	Double Read
					VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read
					VISIT 7	25MAY2016	16:07	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read
Relevant scoliosis	4_5		General		Baseline	20FEB2015	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	Y	Double Read
					VISIT 7	25MAY2016	16:07	Y	Double Read
					VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	20FEB2015	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read
					VISIT 7	25MAY2016	16:07	N	Double Read
					VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	20FEB2015	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read
					VISIT 7	25MAY2016	16:07	N	Double Read
					VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	20FEB2015	16:09	N	Double Read
					VISIT 3A	01JUN2015	15:53	N	Double Read
					VISIT 4	15JUL2015	16:22	N	Double Read
					VISIT 6	24NOV2015	16:42	N	Double Read
					VISIT 7	25MAY2016	16:07	N	Double Read
					VISIT 8	06JUN2017	16:37	N	Double Read
					VISIT 11	10JUN2020	16:09	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	20FEB2015	16:09	84.17568	Double Read
					VISIT 3A	01JUN2015	15:53	82.83744	Double Read
					VISIT 4	15JUL2015	16:22	81.10016	Double Read
					VISIT 6	24NOV2015	16:42	82.02752	Double Read
					VISIT 7	25MAY2016	16:07	80.70064	Double Read
					VISIT 8	06JUN2017	16:37	84.9368	Double Read
					VISIT 11	10JUN2020	16:09	74.05504	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	20FEB2015	16:09	88.90112	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	01JUN2015	15:53	86.24864	Double Read
					VISIT 4	15JUL2015	16:22	86.0904	Double Read
					VISIT 6	24NOV2015	16:42	84.67088	Double Read
					VISIT 7	25MAY2016	16:07	80.89792	Double Read
					VISIT 8	06JUN2017	16:37	85.83008	Double Read
					VISIT 11	10JUN2020	16:09	90.70128	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	20FEB2015	16:09	78.70208	Double Read
					VISIT 3A	01JUN2015	15:53	79.33424	Double Read
					VISIT 4	15JUL2015	16:22	75.95568	Double Read
					VISIT 6	24NOV2015	16:42	75.65008	Double Read
					VISIT 7	25MAY2016	16:07	76.44736	Double Read
					VISIT 8	06JUN2017	16:37	78.288	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	10JUN2020	16:09	74.4112	Double Read
					VISIT 3A	01JUN2015	15:53		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
					VISIT 11	10JUN2020	16:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	20FEB2015	16:09	lower	Double Read
					VISIT 3A	01JUN2015	15:53	equal	Double Read
					VISIT 4	15JUL2015	16:22	equal	Double Read
					VISIT 6	24NOV2015	16:42	lower	Double Read
					VISIT 7	25MAY2016	16:07	lower	Double Read
					VISIT 8	06JUN2017	16:37	lower	Double Read
					VISIT 11	10JUN2020	16:09	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 8	06JUN2017	16:37		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		VISIT 11	10JUN2020	16:09		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	20FEB2015	16:09	higher	Double Read
					VISIT 3A	01JUN2015	15:53	higher	Double Read
					VISIT 4	15JUL2015	16:22	higher	Double Read
					VISIT 6	24NOV2015	16:42	equal	Double Read
					VISIT 7	25MAY2016	16:07	equal	Double Read
					VISIT 8	06JUN2017	16:37	lower	Double Read
					VISIT 11	10JUN2020	16:09	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	20FEB2015	16:09	6.0780023781	Double Read
					VISIT 3A	01JUN2015	15:53	7.3541837948	Double Read
					VISIT 4	15JUL2015	16:22	10.688065228	Double Read
					VISIT 6	24NOV2015	16:42	12.243139120	Double Read
					VISIT 7	25MAY2016	16:07	12.17210124	Double Read
					VISIT 8	06JUN2017	16:37	10.877071513	Double Read
					VISIT 11	10JUN2020	16:09	7.1455953796	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	20FEB2015	16:09	5.8490436555	Double Read
					VISIT 3A	01JUN2015	15:53	6.5681467640	Double Read
					VISIT 4	15JUL2015	16:22	8.4857414642	Double Read
					VISIT 6	24NOV2015	16:42	9.4558654662	Double Read
					VISIT 7	25MAY2016	16:07	2.9556650246	Double Read
					VISIT 8	06JUN2017	16:37	7.4255614064	Double Read
					VISIT 11	10JUN2020	16:09	9.9371496517	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	20FEB2015	16:09	11.829937149	Double Read
					VISIT 3A	01JUN2015	15:53	10.029678953	Double Read
					VISIT 4	15JUL2015	16:22	10.005095974	Double Read
					VISIT 6	24NOV2015	16:42	9.1869067436	Double Read
					VISIT 7	25MAY2016	16:07	7.1381416680	Double Read
					VISIT 8	06JUN2017	16:37	11.592933582	Double Read
					VISIT 11	10JUN2020	16:09	8.7509223713	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	20FEB2015	16:09	19844.5	Double Read
					VISIT 3A	01JUN2015	15:53	20968.5	Double Read
					VISIT 4	15JUL2015	16:22	19585.5	Double Read
					VISIT 6	24NOV2015	16:42	19051.0	Double Read
					VISIT 7	25MAY2016	16:07	20545.5	Double Read
					VISIT 8	06JUN2017	16:37	19777.5	Double Read
					VISIT 11	10JUN2020	16:09	17892.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	20FEB2015	16:09	15191.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	01JUN2015	15:53	14689.5	Double Read
					VISIT 4	15JUL2015	16:22	13634.5	Double Read
					VISIT 6	24NOV2015	16:42	12988.5	Double Read
					VISIT 7	25MAY2016	16:07	13982.0	Double Read
					VISIT 8	06JUN2017	16:37	16696.0	Double Read
					VISIT 11	10JUN2020	16:09	15360.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	20FEB2015	16:09		Double Read
					VISIT 3A	01JUN2015	15:53		Double Read
					VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	20FEB2015	16:09	20201.5	Double Read
					VISIT 3A	01JUN2015	15:53	22107.5	Double Read
					VISIT 4	15JUL2015	16:22	20836.0	Double Read
					VISIT 6	24NOV2015	16:42	19758.5	Double Read
					VISIT 7	25MAY2016	16:07	21489.0	Double Read
					VISIT 8	06JUN2017	16:37	20741.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	10JUN2020	16:09	20532.5	Double Read
					VISIT 3A	01JUN2015	15:53		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0136 Age=46 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	15JUL2015	16:22		Double Read
					VISIT 6	24NOV2015	16:42		Double Read
					VISIT 7	25MAY2016	16:07		Double Read
					VISIT 8	06JUN2017	16:37		Double Read
					VISIT 11	10JUN2020	16:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	25FEB2015	16:58	3	Double Read
					VISIT 3A	01JUN2015	16:54	3	Double Read
					VISIT 4	16JUL2015	15:54	3	Double Read
					VISIT 6	18NOV2015	15:54	3	Double Read
					VISIT 7	01JUN2016	16:22	2	Double Read
					VISIT 8	07JUN2017	16:05	3	Double Read
					VISIT 11	24JUN2020	16:38	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	25FEB2015	16:58	3	Double Read
					VISIT 3A	01JUN2015	16:54	3	Double Read
					VISIT 4	16JUL2015	15:54	3	Double Read
					VISIT 6	18NOV2015	15:54	3	Double Read
					VISIT 7	01JUN2016	16:22	3	Double Read
					VISIT 8	07JUN2017	16:05	4	Double Read
					VISIT 11	24JUN2020	16:38	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	16:58	3	Double Read
					VISIT 3A	01JUN2015	16:54	3	Double Read
					VISIT 4	16JUL2015	15:54	3	Double Read
					VISIT 6	18NOV2015	15:54	3	Double Read
					VISIT 7	01JUN2016	16:22	2	Double Read
					VISIT 8	07JUN2017	16:05	3	Double Read
					VISIT 11	24JUN2020	16:38	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	25FEB2015	16:58	N	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	N	Double Read
					VISIT 6	18NOV2015	15:54	N	Double Read
					VISIT 7	01JUN2016	16:22	N	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	25FEB2015	16:58	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	N	Double Read
					VISIT 6	18NOV2015	15:54	N	Double Read
					VISIT 7	01JUN2016	16:22	N	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	16:58	N	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	N	Double Read
					VISIT 6	18NOV2015	15:54	N	Double Read
					VISIT 7	01JUN2016	16:22	N	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 11	24JUN2020	16:38	N	Double Read
					Baseline	25FEB2015	16:58	N	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	N	Double Read
					VISIT 6	18NOV2015	15:54	N	Double Read
					VISIT 7	01JUN2016	16:22	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read
					Baseline	25FEB2015	16:58	Y	Double Read
					VISIT 3A	01JUN2015	16:54	Y	Double Read
					VISIT 4	16JUL2015	15:54	Y	Double Read
					VISIT 6	18NOV2015	15:54	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	01JUN2016	16:22	Y	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	Y	Double Read
					Baseline	25FEB2015	16:58	N	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	Y	Double Read
					VISIT 6	18NOV2015	15:54	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	01JUN2016	16:22	N	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	25FEB2015	16:58	N	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	N	Double Read
					VISIT 6	18NOV2015	15:54	N	Double Read
					VISIT 7	01JUN2016	16:22	N	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read
Fracture	4_5		General		Baseline	25FEB2015	16:58	N	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	N	Double Read
					VISIT 6	18NOV2015	15:54	N	Double Read
					VISIT 7	01JUN2016	16:22	N	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	25FEB2015	16:58	12.22	Double Read
					VISIT 3A	01JUN2015	16:54	12.485	Double Read
					VISIT 4	16JUL2015	15:54	13.97	Double Read
					VISIT 6	18NOV2015	15:54	12.375	Double Read
					VISIT 7	01JUN2016	16:22	13.235	Double Read
					VISIT 8	07JUN2017	16:05	13.975	Double Read
					VISIT 11	24JUN2020	16:38	11.565	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	25FEB2015	16:58	12.16	Double Read
					VISIT 3A	01JUN2015	16:54	12.2	Double Read
					VISIT 4	16JUL2015	15:54	13.15	Double Read
					VISIT 6	18NOV2015	15:54	11.84	Double Read
					VISIT 7	01JUN2016	16:22	12.9	Double Read
					VISIT 8	07JUN2017	16:05	11.925	Double Read
					VISIT 11	24JUN2020	16:38	12.235	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	25FEB2015	16:58	11.0	Double Read
					VISIT 3A	01JUN2015	16:54	12.21	Double Read
					VISIT 4	16JUL2015	15:54	13.835	Double Read
					VISIT 6	18NOV2015	15:54	12.4	Double Read
					VISIT 7	01JUN2016	16:22	11.62	Double Read
					VISIT 8	07JUN2017	16:05	12.07	Double Read
					VISIT 11	24JUN2020	16:38	11.905	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	25FEB2015	16:58	10.7133	Double Read
					VISIT 3A	01JUN2015	16:54	10.6749	Double Read
					VISIT 4	16JUL2015	15:54	10.1268	Double Read
					VISIT 6	18NOV2015	15:54	9.68786	Double Read
					VISIT 7	01JUN2016	16:22	10.4895	Double Read
					VISIT 8	07JUN2017	16:05	10.482	Double Read
					VISIT 11	24JUN2020	16:38	10.5676	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	25FEB2015	16:58	10.049845	Double Read
					VISIT 3A	01JUN2015	16:54	10.36315	Double Read
					VISIT 4	16JUL2015	15:54	8.82232	Double Read
					VISIT 6	18NOV2015	15:54	9.01812	Double Read
					VISIT 7	01JUN2016	16:22	9.697515	Double Read
					VISIT 8	07JUN2017	16:05	8.14315	Double Read
					VISIT 11	24JUN2020	16:38	6.87729	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	25FEB2015	16:58	10.29669	Double Read
					VISIT 3A	01JUN2015	16:54	10.65256	Double Read
					VISIT 4	16JUL2015	15:54	10.09444	Double Read
					VISIT 6	18NOV2015	15:54	9.991165	Double Read
					VISIT 7	01JUN2016	16:22	10.5594	Double Read
					VISIT 8	07JUN2017	16:05	10.7095	Double Read
					VISIT 11	24JUN2020	16:38	9.78835	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	25FEB2015	16:58	N	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	N	Double Read
					VISIT 6	18NOV2015	15:54	N	Double Read
					VISIT 7	01JUN2016	16:22	N	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	25FEB2015	16:58	N	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	N	Double Read
					VISIT 6	18NOV2015	15:54	N	Double Read
					VISIT 7	01JUN2016	16:22	N	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	16:58	N	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	N	Double Read
					VISIT 6	18NOV2015	15:54	N	Double Read
					VISIT 7	01JUN2016	16:22	N	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	25FEB2015	16:58	N	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	N	Double Read
					VISIT 6	18NOV2015	15:54	N	Double Read
					VISIT 7	01JUN2016	16:22	N	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	25FEB2015	16:58	N	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	N	Double Read
					VISIT 6	18NOV2015	15:54	N	Double Read
					VISIT 7	01JUN2016	16:22	N	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	16:58	N	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	N	Double Read
					VISIT 6	18NOV2015	15:54	N	Double Read
					VISIT 7	01JUN2016	16:22	N	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read
Normal lordotic LS	4_5		General		Baseline	25FEB2015	16:58	Y	Double Read
					VISIT 3A	01JUN2015	16:54	Y	Double Read
					VISIT 4	16JUL2015	15:54	Y	Double Read
					VISIT 6	18NOV2015	15:54	Y	Double Read
					VISIT 7	01JUN2016	16:22	Y	Double Read
					VISIT 8	07JUN2017	16:05	Y	Double Read
					VISIT 11	24JUN2020	16:38	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	25FEB2015	16:58	0	Double Read
					VISIT 3A	01JUN2015	16:54	0	Double Read
					VISIT 4	16JUL2015	15:54	0	Double Read
					VISIT 6	18NOV2015	15:54	0	Double Read
					VISIT 7	01JUN2016	16:22	0	Double Read
					VISIT 8	07JUN2017	16:05	0	Double Read
					VISIT 11	24JUN2020	16:38	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	25FEB2015	16:58	0	Double Read
					VISIT 3A	01JUN2015	16:54	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 4	16JUL2015	15:54	0	Double Read
					VISIT 6	18NOV2015	15:54	0	Double Read
					VISIT 7	01JUN2016	16:22	1	Double Read
					VISIT 8	07JUN2017	16:05	1	Double Read
					VISIT 11	24JUN2020	16:38	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	16:58	0	Double Read
					VISIT 3A	01JUN2015	16:54	0	Double Read
					VISIT 4	16JUL2015	15:54	0	Double Read
					VISIT 6	18NOV2015	15:54	0	Double Read
					VISIT 7	01JUN2016	16:22	0	Double Read
					VISIT 8	07JUN2017	16:05	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 11	24JUN2020	16:38	0	Double Read
					Baseline	25FEB2015	16:58	N	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	N	Double Read
					VISIT 6	18NOV2015	15:54	N	Double Read
					VISIT 7	01JUN2016	16:22	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read
					Baseline	25FEB2015	16:58	N	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	N	Double Read
					VISIT 6	18NOV2015	15:54	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	01JUN2016	16:22	N	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read
					Baseline	25FEB2015	16:58	N	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	N	Double Read
					VISIT 6	18NOV2015	15:54	N	Double Read
					VISIT 7	01JUN2016	16:22	N	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read
Relevant scoliosis	4_5		General		Baseline	25FEB2015	16:58	Y	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	Y	Double Read
					VISIT 6	18NOV2015	15:54	Y	Double Read
					VISIT 7	01JUN2016	16:22	Y	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	25FEB2015	16:58	N	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	N	Double Read
					VISIT 6	18NOV2015	15:54	N	Double Read
					VISIT 7	01JUN2016	16:22	N	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	25FEB2015	16:58	N	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	N	Double Read
					VISIT 6	18NOV2015	15:54	N	Double Read
					VISIT 7	01JUN2016	16:22	N	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	16:58	N	Double Read
					VISIT 3A	01JUN2015	16:54	N	Double Read
					VISIT 4	16JUL2015	15:54	N	Double Read
					VISIT 6	18NOV2015	15:54	N	Double Read
					VISIT 7	01JUN2016	16:22	N	Double Read
					VISIT 8	07JUN2017	16:05	N	Double Read
					VISIT 11	24JUN2020	16:38	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	25FEB2015	16:58	70.7144	Double Read
					VISIT 3A	01JUN2015	16:54	69.63248	Double Read
					VISIT 4	16JUL2015	15:54	71.88752	Double Read
					VISIT 6	18NOV2015	15:54	69.27936	Double Read
					VISIT 7	01JUN2016	16:22	70.29616	Double Read
					VISIT 8	07JUN2017	16:05	75.00368	Double Read
					VISIT 11	24JUN2020	16:38	62.58496	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	25FEB2015	16:58	72.53952	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	01JUN2015	16:54	66.80192	Double Read
					VISIT 4	16JUL2015	15:54	75.41792	Double Read
					VISIT 6	18NOV2015	15:54	69.03184	Double Read
					VISIT 7	01JUN2016	16:22	66.88768	Double Read
					VISIT 8	07JUN2017	16:05	65.944	Double Read
					VISIT 11	24JUN2020	16:38	61.64832	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	VISIT 11	24JUN2020	16:38		Double Read
					Baseline	25FEB2015	16:58	69.72336	Double Read
					VISIT 3A	01JUN2015	16:54	71.01776	Double Read
					VISIT 4	16JUL2015	15:54	72.25152	Double Read
					VISIT 6	18NOV2015	15:54	66.34336	Double Read
					VISIT 7	01JUN2016	16:22	74.61696	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	07JUN2017	16:05	76.22624	Double Read
					VISIT 11	24JUN2020	16:38	66.38608	Double Read
					Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	25FEB2015	16:58	equal	Double Read
					VISIT 3A	01JUN2015	16:54	lower	Double Read
					VISIT 4	16JUL2015	15:54	equal	Double Read
					VISIT 6	18NOV2015	15:54	equal	Double Read
					VISIT 7	01JUN2016	16:22	lower	Double Read
					VISIT 8	07JUN2017	16:05	lower	Double Read
					VISIT 11	24JUN2020	16:38	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		VISIT 11	24JUN2020	16:38		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	25FEB2015	16:58	equal	Double Read
					VISIT 3A	01JUN2015	16:54	equal	Double Read
					VISIT 4	16JUL2015	15:54	equal	Double Read
					VISIT 6	18NOV2015	15:54	equal	Double Read
					VISIT 7	01JUN2016	16:22	lower	Double Read
					VISIT 8	07JUN2017	16:05	lower	Double Read
					VISIT 11	24JUN2020	16:38	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	25FEB2015	16:58	7.2945269237	Double Read
					VISIT 3A	01JUN2015	16:54	8.1431085442	Double Read
					VISIT 4	16JUL2015	15:54	9.4372617631	Double Read
					VISIT 6	18NOV2015	15:54	8.2984474265	Double Read
					VISIT 7	01JUN2016	16:22	9.8097502972	Double Read
					VISIT 8	07JUN2017	16:05	7.5299269577	Double Read
					VISIT 11	24JUN2020	16:38	6.5849974520	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	25FEB2015	16:58	11.360930864	Double Read
					VISIT 3A	01JUN2015	16:54	6 7.9157465602	Double Read
					VISIT 4	16JUL2015	15:54	2 5.5631051469	Double Read
					VISIT 6	18NOV2015	15:54	3 8.8815559707	Double Read
					VISIT 7	01JUN2016	16:22	9 4.2898861899	Double Read
					VISIT 8	07JUN2017	16:05	1 11.992525904	Double Read
					VISIT 11	24JUN2020	16:38	5 8.3800441651	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	25FEB2015	16:58	3.5462272804	Double Read
					VISIT 3A	01JUN2015	16:54	8.9689145574	Double Read
					VISIT 4	16JUL2015	15:54	9.6257244776	Double Read
					VISIT 6	18NOV2015	15:54	10.033409206	Double Read
					VISIT 7	01JUN2016	16:22	6.7993477153	Double Read
					VISIT 8	07JUN2017	16:05	7.9584712077	Double Read
					VISIT 11	24JUN2020	16:38	3.9940207236	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	25FEB2015	16:58	9952.5	Double Read
					VISIT 3A	01JUN2015	16:54	10045.5	Double Read
					VISIT 4	16JUL2015	15:54	9961.0	Double Read
					VISIT 6	18NOV2015	15:54	9519.0	Double Read
					VISIT 7	01JUN2016	16:22	9898.5	Double Read
					VISIT 8	07JUN2017	16:05	10269.5	Double Read
					VISIT 11	24JUN2020	16:38	9437.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	25FEB2015	16:58	10699.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	01JUN2015	16:54	10392.5	Double Read
					VISIT 4	16JUL2015	15:54	10250.5	Double Read
					VISIT 6	18NOV2015	15:54	9402.0	Double Read
					VISIT 7	01JUN2016	16:22	10071.0	Double Read
					VISIT 8	07JUN2017	16:05	9925.5	Double Read
					VISIT 11	24JUN2020	16:38	9242.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	25FEB2015	16:58		Double Read
					VISIT 3A	01JUN2015	16:54		Double Read
					VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	25FEB2015	16:58	10585.5	Double Read
					VISIT 3A	01JUN2015	16:54	11473.0	Double Read
					VISIT 4	16JUL2015	15:54	11309.0	Double Read
					VISIT 6	18NOV2015	15:54	10337.5	Double Read
					VISIT 7	01JUN2016	16:22	10688.5	Double Read
					VISIT 8	07JUN2017	16:05	11573.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	24JUN2020	16:38	10264.0	Double Read
					VISIT 3A	01JUN2015	16:54		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0137 Age=49 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	16JUL2015	15:54		Double Read
					VISIT 6	18NOV2015	15:54		Double Read
					VISIT 7	01JUN2016	16:22		Double Read
					VISIT 8	07JUN2017	16:05		Double Read
					VISIT 11	24JUN2020	16:38		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	05MAR2015	16:36	3	Double Read
					VISIT 4	23APR2015	15:57	3	Double Read
					VISIT 6	15SEP2015	16:16	4	Double Read
					VISIT 7	24FEB2016	16:32	3	Double Read
					VISIT 8	08FEB2017	15:58	3	Double Read
					VISIT 11	12FEB2020	16:00	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	05MAR2015	16:36	3	Double Read
					VISIT 4	23APR2015	15:57	3	Double Read
					VISIT 6	15SEP2015	16:16	3	Double Read
					VISIT 7	24FEB2016	16:32	3	Double Read
					VISIT 8	08FEB2017	15:58	3	Double Read
					VISIT 11	12FEB2020	16:00	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	05MAR2015	16:36	N	Double Read
					VISIT 4	23APR2015	15:57	N	Double Read
					VISIT 6	15SEP2015	16:16	N	Double Read
					VISIT 7	24FEB2016	16:32	N	Double Read
					VISIT 8	08FEB2017	15:58	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 11	12FEB2020	16:00	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	05MAR2015	16:36	N	Double Read
					VISIT 4	23APR2015	15:57	N	Double Read
					VISIT 6	15SEP2015	16:16	N	Double Read
					VISIT 7	24FEB2016	16:32	N	Double Read
					VISIT 8	08FEB2017	15:58	N	Double Read
					VISIT 11	12FEB2020	16:00	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	05MAR2015	16:36	Y	Double Read
					VISIT 4	23APR2015	15:57	Y	Double Read
					VISIT 6	15SEP2015	16:16	N	Double Read
					VISIT 7	24FEB2016	16:32	N	Double Read
					VISIT 8	08FEB2017	15:58	N	Double Read
					VISIT 11	12FEB2020	16:00	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	05MAR2015	16:36	N	Double Read
					VISIT 4	23APR2015	15:57	Y	Double Read
					VISIT 6	15SEP2015	16:16	N	Double Read
					VISIT 7	24FEB2016	16:32	N	Double Read
					VISIT 8	08FEB2017	15:58	N	Double Read
					VISIT 11	12FEB2020	16:00	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	05MAR2015	16:36	N	Double Read
					VISIT 4	23APR2015	15:57	N	Double Read
					VISIT 6	15SEP2015	16:16	N	Double Read
					VISIT 7	24FEB2016	16:32	N	Double Read
					VISIT 8	08FEB2017	15:58	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 11	12FEB2020	16:00	N	Double Read
Fracture	5_S		General		Baseline	05MAR2015	16:36	N	Double Read
					VISIT 4	23APR2015	15:57	N	Double Read
					VISIT 6	15SEP2015	16:16	N	Double Read
					VISIT 7	24FEB2016	16:32	N	Double Read
					VISIT 8	08FEB2017	15:58	N	Double Read
					VISIT 11	12FEB2020	16:00	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	05MAR2015	16:36	10.19	Double Read
					VISIT 4	23APR2015	15:57	10.32	Double Read
					VISIT 6	15SEP2015	16:16	12.31	Double Read
					VISIT 7	24FEB2016	16:32	11.865	Double Read
					VISIT 8	08FEB2017	15:58	11.445	Double Read
					VISIT 11	12FEB2020	16:00	10.145	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	05MAR2015	16:36	11.345	Double Read
					VISIT 4	23APR2015	15:57	11.455	Double Read
					VISIT 6	15SEP2015	16:16	11.965	Double Read
					VISIT 7	24FEB2016	16:32	14.455	Double Read
					VISIT 8	08FEB2017	15:58	12.765	Double Read
					VISIT 11	12FEB2020	16:00	12.18	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	05MAR2015	16:36	6.07851	Double Read
					VISIT 4	23APR2015	15:57	6.4123	Double Read
					VISIT 6	15SEP2015	16:16	6.41355	Double Read
					VISIT 7	24FEB2016	16:32	6.260985	Double Read
					VISIT 8	08FEB2017	15:58	6.21477	Double Read
					VISIT 11	12FEB2020	16:00	6.22375	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	05MAR2015	16:36	9.06799	Double Read
					VISIT 4	23APR2015	15:57	9.27885	Double Read
					VISIT 6	15SEP2015	16:16	9.89783	Double Read
					VISIT 7	24FEB2016	16:32	9.18807	Double Read
					VISIT 8	08FEB2017	15:58	9.34154	Double Read
					VISIT 11	12FEB2020	16:00	9.3589	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	05MAR2015	16:36	N	Double Read
					VISIT 4	23APR2015	15:57	N	Double Read
					VISIT 6	15SEP2015	16:16	N	Double Read
					VISIT 7	24FEB2016	16:32	N	Double Read
					VISIT 8	08FEB2017	15:58	N	Double Read
					VISIT 11	12FEB2020	16:00	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	05MAR2015	16:36	N	Double Read
					VISIT 4	23APR2015	15:57	N	Double Read
					VISIT 6	15SEP2015	16:16	N	Double Read
					VISIT 7	24FEB2016	16:32	N	Double Read
					VISIT 8	08FEB2017	15:58	N	Double Read
					VISIT 11	12FEB2020	16:00	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	05MAR2015	16:36	N	Double Read
					VISIT 4	23APR2015	15:57	N	Double Read
					VISIT 6	15SEP2015	16:16	N	Double Read
					VISIT 7	24FEB2016	16:32	N	Double Read
					VISIT 8	08FEB2017	15:58	N	Double Read
					VISIT 11	12FEB2020	16:00	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	05MAR2015	16:36	N	Double Read
					VISIT 4	23APR2015	15:57	N	Double Read
					VISIT 6	15SEP2015	16:16	N	Double Read
					VISIT 7	24FEB2016	16:32	N	Double Read
					VISIT 8	08FEB2017	15:58	N	Double Read
					VISIT 11	12FEB2020	16:00	N	Double Read
Normal lordotic LS	5_S		General		Baseline	05MAR2015	16:36	Y	Double Read
					VISIT 4	23APR2015	15:57	N	Double Read
					VISIT 6	15SEP2015	16:16	Y	Double Read
					VISIT 7	24FEB2016	16:32	Y	Double Read
					VISIT 8	08FEB2017	15:58	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	5_S		General		VISIT 11	12FEB2020	16:00	N	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	05MAR2015	16:36	0	Double Read
					VISIT 4	23APR2015	15:57	0	Double Read
					VISIT 6	15SEP2015	16:16	0	Double Read
					VISIT 7	24FEB2016	16:32	0	Double Read
					VISIT 8	08FEB2017	15:58	0	Double Read
					VISIT 11	12FEB2020	16:00	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	05MAR2015	16:36	0	Double Read
					VISIT 4	23APR2015	15:57	0	Double Read
					VISIT 6	15SEP2015	16:16	0	Double Read
					VISIT 7	24FEB2016	16:32	0	Double Read
					VISIT 8	08FEB2017	15:58	0	Double Read
					VISIT 11	12FEB2020	16:00	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	05MAR2015	16:36	N	Double Read
					VISIT 4	23APR2015	15:57	N	Double Read
					VISIT 6	15SEP2015	16:16	N	Double Read
					VISIT 7	24FEB2016	16:32	N	Double Read
					VISIT 8	08FEB2017	15:58	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 11	12FEB2020	16:00	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	05MAR2015	16:36	N	Double Read
					VISIT 4	23APR2015	15:57	N	Double Read
					VISIT 6	15SEP2015	16:16	N	Double Read
					VISIT 7	24FEB2016	16:32	N	Double Read
					VISIT 8	08FEB2017	15:58	N	Double Read
					VISIT 11	12FEB2020	16:00	N	Double Read
Relevant scoliosis	5_S		General		Baseline	05MAR2015	16:36	N	Double Read
					VISIT 4	23APR2015	15:57	N	Double Read
					VISIT 6	15SEP2015	16:16	N	Double Read
					VISIT 7	24FEB2016	16:32	N	Double Read
					VISIT 8	08FEB2017	15:58	N	Double Read
					VISIT 11	12FEB2020	16:00	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	05MAR2015	16:36	N	Double Read
					VISIT 4	23APR2015	15:57	N	Double Read
					VISIT 6	15SEP2015	16:16	N	Double Read
					VISIT 7	24FEB2016	16:32	N	Double Read
					VISIT 8	08FEB2017	15:58	N	Double Read
					VISIT 11	12FEB2020	16:00	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	05MAR2015	16:36	N	Double Read
					VISIT 4	23APR2015	15:57	N	Double Read
					VISIT 6	15SEP2015	16:16	N	Double Read
					VISIT 7	24FEB2016	16:32	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	08FEB2017	15:58	N	Double Read
					VISIT 11	12FEB2020	16:00	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	05MAR2015	16:36	72.85456	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 4	23APR2015	15:57	78.3224	Double Read
					VISIT 6	15SEP2015	16:16	81.744	Double Read
					VISIT 7	24FEB2016	16:32	86.79904	Double Read
					VISIT 8	08FEB2017	15:58	95.83952	Double Read
					VISIT 11	12FEB2020	16:00	71.39168	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	05MAR2015	16:36	75.88864	Double Read
					VISIT 4	23APR2015	15:57	76.5328	Double Read
					VISIT 6	15SEP2015	16:16	69.75696	Double Read
					VISIT 7	24FEB2016	16:32	72.80464	Double Read
					VISIT 8	08FEB2017	15:58	74.00992	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	12FEB2020	16:00	63.92224	Double Read
					Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	05MAR2015	16:36	equal	Double Read
					VISIT 4	23APR2015	15:57	equal	Double Read
					VISIT 6	15SEP2015	16:16	equal	Double Read
					VISIT 7	24FEB2016	16:32	equal	Double Read
					VISIT 8	08FEB2017	15:58	equal	Double Read
					VISIT 11	12FEB2020	16:00	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	05MAR2015	16:36	7.4862306777	Double Read
					VISIT 4	23APR2015	15:57	3.4681229828	Double Read
					VISIT 6	15SEP2015	16:16	2.2881943264	Double Read
					VISIT 7	24FEB2016	16:32	4.0816307117	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	08FEB2017	15:58	2.0788381178	Double Read 8
					VISIT 11	12FEB2020	16:00	1.9915678613	Double Read 9
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	05MAR2015	16:36	4.8387497876	Double Read 6
					VISIT 4	23APR2015	15:57	9.6540377102	Double Read 1
					VISIT 6	15SEP2015	16:16	5.5813079667	Double Read 1
					VISIT 7	24FEB2016	16:32	10.105296415	Double Read 8
					VISIT 8	08FEB2017	15:58	10.475060302	Double Read 3
					VISIT 11	12FEB2020	16:00	7.2579038559	Double Read 5
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	05MAR2015	16:36	8209.5	Double Read
					VISIT 4	23APR2015	15:57	8225.5	Double Read
					VISIT 6	15SEP2015	16:16	8700.5	Double Read
					VISIT 7	24FEB2016	16:32	9531.0	Double Read
					VISIT 8	08FEB2017	15:58	7980.0	Double Read
					VISIT 11	12FEB2020	16:00	7163.0	Double Read
Volume (mm ³) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
Volume (mm ³) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read
					VISIT 11	12FEB2020	16:00		Double Read
Volume (mm ³) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	05MAR2015	16:36	12084.5	Double Read
					VISIT 4	23APR2015	15:57	12656.0	Double Read
					VISIT 6	15SEP2015	16:16	13256.5	Double Read
					VISIT 7	24FEB2016	16:32	13933.0	Double Read
					VISIT 8	08FEB2017	15:58	12437.5	Double Read
					VISIT 11	12FEB2020	16:00	12700.0	Double Read
Volume (mm ³) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	05MAR2015	16:36		Double Read
					VISIT 4	23APR2015	15:57		Double Read
					VISIT 6	15SEP2015	16:16		Double Read
					VISIT 7	24FEB2016	16:32		Double Read
					VISIT 8	08FEB2017	15:58		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0138 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	12FEB2020	16:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0139 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	09MAR2015	17:48	3	Double Read
					VISIT 3A	02JUN2015	16:15	4	Double Read
					VISIT 4	14JUL2015	16:18	3	Double Read
					VISIT 6	02DEC2015	16:00	4	Double Read
					VISIT 7	15JUN2016	16:10	3	Double Read
					VISIT 8	07JUN2017	16:52	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	09MAR2015	17:48	2	Double Read
					VISIT 3A	02JUN2015	16:15	2	Double Read
					VISIT 4	14JUL2015	16:18	2	Double Read
					VISIT 6	02DEC2015	16:00	2	Double Read
					VISIT 7	15JUN2016	16:10	2	Double Read
					VISIT 8	07JUN2017	16:52	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	09MAR2015	17:48	N	Double Read
					VISIT 3A	02JUN2015	16:15	N	Double Read
					VISIT 4	14JUL2015	16:18	N	Double Read
					VISIT 6	02DEC2015	16:00	N	Double Read
					VISIT 7	15JUN2016	16:10	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0139 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 8	07JUN2017	16:52	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	09MAR2015	17:48	N	Double Read
					VISIT 3A	02JUN2015	16:15	N	Double Read
					VISIT 4	14JUL2015	16:18	N	Double Read
					VISIT 6	02DEC2015	16:00	N	Double Read
					VISIT 7	15JUN2016	16:10	N	Double Read
					VISIT 8	07JUN2017	16:52	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	09MAR2015	17:48	Y	Double Read
					VISIT 3A	02JUN2015	16:15	Y	Double Read
					VISIT 4	14JUL2015	16:18	Y	Double Read
					VISIT 6	02DEC2015	16:00	N	Double Read
					VISIT 7	15JUN2016	16:10	Y	Double Read
					VISIT 8	07JUN2017	16:52	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	09MAR2015	17:48	N	Double Read
					VISIT 3A	02JUN2015	16:15	N	Double Read
					VISIT 4	14JUL2015	16:18	N	Double Read
					VISIT 6	02DEC2015	16:00	N	Double Read
					VISIT 7	15JUN2016	16:10	N	Double Read
					VISIT 8	07JUN2017	16:52	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	09MAR2015	17:48	N	Double Read
					VISIT 3A	02JUN2015	16:15	N	Double Read
					VISIT 4	14JUL2015	16:18	N	Double Read
					VISIT 6	02DEC2015	16:00	N	Double Read
					VISIT 7	15JUN2016	16:10	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0139 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 8	07JUN2017	16:52	N	Double Read
Fracture	5_S		General		Baseline	09MAR2015	17:48	N	Double Read
					VISIT 3A	02JUN2015	16:15	N	Double Read
					VISIT 4	14JUL2015	16:18	N	Double Read
					VISIT 6	02DEC2015	16:00	N	Double Read
					VISIT 7	15JUN2016	16:10	N	Double Read
					VISIT 8	07JUN2017	16:52	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	09MAR2015	17:48	13.955	Double Read
					VISIT 3A	02JUN2015	16:15	13.195	Double Read
					VISIT 4	14JUL2015	16:18	14.64	Double Read
					VISIT 6	02DEC2015	16:00	13.095	Double Read
					VISIT 7	15JUN2016	16:10	13.555	Double Read
					VISIT 8	07JUN2017	16:52	11.79	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	09MAR2015	17:48	16.36	Double Read
					VISIT 3A	02JUN2015	16:15	14.515	Double Read
					VISIT 4	14JUL2015	16:18	15.245	Double Read
					VISIT 6	02DEC2015	16:00	14.57	Double Read
					VISIT 7	15JUN2016	16:10	16.54	Double Read
					VISIT 8	07JUN2017	16:52	17.005	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0139 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	09MAR2015	17:48	8.59414	Double Read
					VISIT 3A	02JUN2015	16:15	7.783185	Double Read
					VISIT 4	14JUL2015	16:18	8.359035	Double Read
					VISIT 6	02DEC2015	16:00	8.61169	Double Read
					VISIT 7	15JUN2016	16:10	7.632855	Double Read
					VISIT 8	07JUN2017	16:52	7.275545	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	09MAR2015	17:48	11.46025	Double Read
					VISIT 3A	02JUN2015	16:15	11.5462	Double Read
					VISIT 4	14JUL2015	16:18	10.31482	Double Read
					VISIT 6	02DEC2015	16:00	10.6197	Double Read
					VISIT 7	15JUN2016	16:10	10.6022	Double Read
					VISIT 8	07JUN2017	16:52	11.4405	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	09MAR2015	17:48	N	Double Read
					VISIT 3A	02JUN2015	16:15	N	Double Read
					VISIT 4	14JUL2015	16:18	N	Double Read
					VISIT 6	02DEC2015	16:00	N	Double Read
					VISIT 7	15JUN2016	16:10	N	Double Read
					VISIT 8	07JUN2017	16:52	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0139 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	09MAR2015	17:48	N	Double Read
					VISIT 3A	02JUN2015	16:15	N	Double Read
					VISIT 4	14JUL2015	16:18	N	Double Read
					VISIT 6	02DEC2015	16:00	N	Double Read
					VISIT 7	15JUN2016	16:10	N	Double Read
					VISIT 8	07JUN2017	16:52	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	09MAR2015	17:48	N	Double Read
					VISIT 3A	02JUN2015	16:15	N	Double Read
					VISIT 4	14JUL2015	16:18	N	Double Read
					VISIT 6	02DEC2015	16:00	N	Double Read
					VISIT 7	15JUN2016	16:10	N	Double Read
					VISIT 8	07JUN2017	16:52	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	09MAR2015	17:48	N	Double Read
					VISIT 3A	02JUN2015	16:15	N	Double Read
					VISIT 4	14JUL2015	16:18	N	Double Read
					VISIT 6	02DEC2015	16:00	N	Double Read
					VISIT 7	15JUN2016	16:10	N	Double Read
					VISIT 8	07JUN2017	16:52	N	Double Read
Normal lordotic LS	5_S		General		Baseline	09MAR2015	17:48	Y	Double Read
					VISIT 3A	02JUN2015	16:15	Y	Double Read
					VISIT 4	14JUL2015	16:18	Y	Double Read
					VISIT 6	02DEC2015	16:00	Y	Double Read
					VISIT 7	15JUN2016	16:10	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0139 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	5_S		General		VISIT 8	07JUN2017	16:52	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	09MAR2015	17:48	0	Double Read
					VISIT 3A	02JUN2015	16:15	0	Double Read
					VISIT 4	14JUL2015	16:18	2	Double Read
					VISIT 6	02DEC2015	16:00	2	Double Read
					VISIT 7	15JUN2016	16:10	0	Double Read
					VISIT 8	07JUN2017	16:52	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	09MAR2015	17:48	0	Double Read
					VISIT 3A	02JUN2015	16:15	0	Double Read
					VISIT 4	14JUL2015	16:18	0	Double Read
					VISIT 6	02DEC2015	16:00	0	Double Read
					VISIT 7	15JUN2016	16:10	0	Double Read
					VISIT 8	07JUN2017	16:52	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	09MAR2015	17:48	N	Double Read
					VISIT 3A	02JUN2015	16:15	N	Double Read
					VISIT 4	14JUL2015	16:18	N	Double Read
					VISIT 6	02DEC2015	16:00	N	Double Read
					VISIT 7	15JUN2016	16:10	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0139 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	07JUN2017	16:52	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	09MAR2015	17:48	N	Double Read
					VISIT 3A	02JUN2015	16:15	N	Double Read
					VISIT 4	14JUL2015	16:18	N	Double Read
					VISIT 6	02DEC2015	16:00	N	Double Read
					VISIT 7	15JUN2016	16:10	N	Double Read
					VISIT 8	07JUN2017	16:52	N	Double Read
Relevant scoliosis	5_S		General		Baseline	09MAR2015	17:48	N	Double Read
					VISIT 3A	02JUN2015	16:15	N	Double Read
					VISIT 4	14JUL2015	16:18	N	Double Read
					VISIT 6	02DEC2015	16:00	N	Double Read
					VISIT 7	15JUN2016	16:10	N	Double Read
					VISIT 8	07JUN2017	16:52	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	09MAR2015	17:48	N	Double Read
					VISIT 3A	02JUN2015	16:15	N	Double Read
					VISIT 4	14JUL2015	16:18	N	Double Read
					VISIT 6	02DEC2015	16:00	N	Double Read
					VISIT 7	15JUN2016	16:10	N	Double Read
					VISIT 8	07JUN2017	16:52	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	09MAR2015	17:48	N	Double Read
					VISIT 3A	02JUN2015	16:15	N	Double Read
					VISIT 4	14JUL2015	16:18	N	Double Read
					VISIT 6	02DEC2015	16:00	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0139 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	15JUN2016	16:10	N	Double Read
					VISIT 8	07JUN2017	16:52	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	09MAR2015	17:48	80.12864	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0139 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	02JUN2015	16:15	82.5592	Double Read
					VISIT 4	14JUL2015	16:18	83.13168	Double Read
					VISIT 6	02DEC2015	16:00	80.9632	Double Read
					VISIT 7	15JUN2016	16:10	81.29872	Double Read
					VISIT 8	07JUN2017	16:52	80.6056	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	09MAR2015	17:48	109.3472	Double Read
					VISIT 3A	02JUN2015	16:15	113.70144	Double Read
					VISIT 4	14JUL2015	16:18	109.98768	Double Read
					VISIT 6	02DEC2015	16:00	113.396	Double Read
					VISIT 7	15JUN2016	16:10	114.63872	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	07JUN2017	16:52	109.87264	Double Read
					Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0139 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0139 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	09MAR2015	17:48	lower	Double Read
					VISIT 3A	02JUN2015	16:15	lower	Double Read
					VISIT 4	14JUL2015	16:18	lower	Double Read
					VISIT 6	02DEC2015	16:00	lower	Double Read
					VISIT 7	15JUN2016	16:10	lower	Double Read
					VISIT 8	07JUN2017	16:52	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0139 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0139 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	09MAR2015	17:48	6.5483268218	Double Read
					VISIT 3A	02JUN2015	16:15	10.2108238491	Double Read
					VISIT 4	14JUL2015	16:18	5.39967385765	Double Read
					VISIT 6	02DEC2015	16:00	6.48321386105	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0139 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 7	15JUN2016	16:10	7.32310514693	Double Read
					VISIT 8	07JUN2017	16:52	7.6694411415	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	09MAR2015	17:48	2.17266519449	Double Read
					VISIT 3A	02JUN2015	16:15	3.29620519789	Double Read
					VISIT 4	14JUL2015	16:18	3.1821505011	Double Read
					VISIT 6	02DEC2015	16:00	4.75624256837	Double Read
					VISIT 7	15JUN2016	16:10	3.51056225582	Double Read
					VISIT 8	07JUN2017	16:52	3.51055546119	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0139 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	07JUN2017	16:52		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	09MAR2015	17:48	12135.5	Double Read
					VISIT 3A	02JUN2015	16:15	10923.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0139 Age=29 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 4	14JUL2015	16:18	11135.0	Double Read
					VISIT 6	02DEC2015	16:00	12016.5	Double Read
					VISIT 7	15JUN2016	16:10	11732.5	Double Read
					VISIT 8	07JUN2017	16:52	11713.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	09MAR2015	17:48	17231.0	Double Read
					VISIT 3A	02JUN2015	16:15	16660.0	Double Read
					VISIT 4	14JUL2015	16:18	16789.5	Double Read
					VISIT 6	02DEC2015	16:00	15785.0	Double Read
					VISIT 7	15JUN2016	16:10	17198.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	09MAR2015	17:48		Double Read
					VISIT 3A	02JUN2015	16:15		Double Read
					VISIT 4	14JUL2015	16:18		Double Read
					VISIT 6	02DEC2015	16:00		Double Read
					VISIT 7	15JUN2016	16:10		Double Read
					VISIT 8	07JUN2017	16:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	11MAY2015	16:15	4	Double Read
					VISIT 3A	10AUG2015	15:44	4	Double Read
					VISIT 4	22SEP2015	16:13	4	Double Read
					VISIT 6	08FEB2016	15:53	4	Double Read
					VISIT 7	27JUL2016	16:37	4	Double Read
					VISIT 8	26JUL2017	15:50	4	Double Read
					VISIT 11	19AUG2020	15:54	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	16:15	3	Double Read
					VISIT 3A	10AUG2015	15:44	3	Double Read
					VISIT 4	22SEP2015	16:13	3	Double Read
					VISIT 6	08FEB2016	15:53	3	Double Read
					VISIT 7	27JUL2016	16:37	3	Double Read
					VISIT 8	26JUL2017	15:50	3	Double Read
					VISIT 11	19AUG2020	15:54	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	11MAY2015	16:15	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	10AUG2015	15:44	N	Double Read
					VISIT 4	22SEP2015	16:13	N	Double Read
					VISIT 6	08FEB2016	15:53	N	Double Read
					VISIT 7	27JUL2016	16:37	N	Double Read
					VISIT 8	26JUL2017	15:50	N	Double Read
					VISIT 11	19AUG2020	15:54	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	16:15	N	Double Read
					VISIT 3A	10AUG2015	15:44	N	Double Read
					VISIT 4	22SEP2015	16:13	N	Double Read
					VISIT 6	08FEB2016	15:53	N	Double Read
					VISIT 7	27JUL2016	16:37	N	Double Read
					VISIT 8	26JUL2017	15:50	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	19AUG2020	15:54	N	Double Read
					Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
					Baseline	11MAY2015	16:15	Y	Double Read
					VISIT 3A	10AUG2015	15:44	Y	Double Read
					VISIT 4	22SEP2015	16:13	Y	Double Read
					VISIT 6	08FEB2016	15:53	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	27JUL2016	16:37	Y	Double Read
					VISIT 8	26JUL2017	15:50	Y	Double Read
					VISIT 11	19AUG2020	15:54	Y	Double Read
					Baseline	11MAY2015	16:15	N	Double Read
					VISIT 3A	10AUG2015	15:44	N	Double Read
					VISIT 4	22SEP2015	16:13	N	Double Read
					VISIT 6	08FEB2016	15:53	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	27JUL2016	16:37	N	Double Read
					VISIT 8	26JUL2017	15:50	N	Double Read
					VISIT 11	19AUG2020	15:54	Y	Double Read
Extradiscal fluid collection	5_S		General		Baseline	11MAY2015	16:15	N	Double Read
					VISIT 3A	10AUG2015	15:44	N	Double Read
					VISIT 4	22SEP2015	16:13	N	Double Read
					VISIT 6	08FEB2016	15:53	N	Double Read
					VISIT 7	27JUL2016	16:37	N	Double Read
					VISIT 8	26JUL2017	15:50	N	Double Read
					VISIT 11	19AUG2020	15:54	N	Double Read
Fracture	5_S		General		Baseline	11MAY2015	16:15	N	Double Read
					VISIT 3A	10AUG2015	15:44	N	Double Read
					VISIT 4	22SEP2015	16:13	N	Double Read
					VISIT 6	08FEB2016	15:53	N	Double Read
					VISIT 7	27JUL2016	16:37	N	Double Read
					VISIT 8	26JUL2017	15:50	N	Double Read
					VISIT 11	19AUG2020	15:54	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11MAY2015	16:15	14.89	Double Read
					VISIT 3A	10AUG2015	15:44	14.665	Double Read
					VISIT 4	22SEP2015	16:13	12.845	Double Read
					VISIT 6	08FEB2016	15:53	13.88	Double Read
					VISIT 7	27JUL2016	16:37	15.73	Double Read
					VISIT 8	26JUL2017	15:50	13.885	Double Read
					VISIT 11	19AUG2020	15:54	15.11	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11MAY2015	16:15	13.8	Double Read
					VISIT 3A	10AUG2015	15:44	28.635	Double Read
					VISIT 4	22SEP2015	16:13	14.155	Double Read
					VISIT 6	08FEB2016	15:53	14.425	Double Read
					VISIT 7	27JUL2016	16:37	14.51	Double Read
					VISIT 8	26JUL2017	15:50	14.78	Double Read
					VISIT 11	19AUG2020	15:54	14.825	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11MAY2015	16:15	6.154675	Double Read
					VISIT 3A	10AUG2015	15:44	4.97869	Double Read
					VISIT 4	22SEP2015	16:13	5.55256	Double Read
					VISIT 6	08FEB2016	15:53	6.25185	Double Read
					VISIT 7	27JUL2016	16:37	5.56943	Double Read
					VISIT 8	26JUL2017	15:50	5.884985	Double Read
					VISIT 11	19AUG2020	15:54	5.913805	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11MAY2015	16:15	9.938605	Double Read
					VISIT 3A	10AUG2015	15:44	9.533925	Double Read
					VISIT 4	22SEP2015	16:13	9.6841	Double Read
					VISIT 6	08FEB2016	15:53	10.018785	Double Read
					VISIT 7	27JUL2016	16:37	9.91654	Double Read
					VISIT 8	26JUL2017	15:50	10.2056	Double Read
					VISIT 11	19AUG2020	15:54	9.62851	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	11MAY2015	16:15	N	Double Read
					VISIT 3A	10AUG2015	15:44	N	Double Read
					VISIT 4	22SEP2015	16:13	N	Double Read
					VISIT 6	08FEB2016	15:53	N	Double Read
					VISIT 7	27JUL2016	16:37	N	Double Read
					VISIT 8	26JUL2017	15:50	N	Double Read
					VISIT 11	19AUG2020	15:54	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	16:15	N	Double Read
					VISIT 3A	10AUG2015	15:44	N	Double Read
					VISIT 4	22SEP2015	16:13	N	Double Read
					VISIT 6	08FEB2016	15:53	N	Double Read
					VISIT 7	27JUL2016	16:37	N	Double Read
					VISIT 8	26JUL2017	15:50	N	Double Read
					VISIT 11	19AUG2020	15:54	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	11MAY2015	16:15	N	Double Read
					VISIT 3A	10AUG2015	15:44	N	Double Read
					VISIT 4	22SEP2015	16:13	N	Double Read
					VISIT 6	08FEB2016	15:53	N	Double Read
					VISIT 7	27JUL2016	16:37	N	Double Read
					VISIT 8	26JUL2017	15:50	N	Double Read
					VISIT 11	19AUG2020	15:54	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	16:15	N	Double Read
					VISIT 3A	10AUG2015	15:44	N	Double Read
					VISIT 4	22SEP2015	16:13	N	Double Read
					VISIT 6	08FEB2016	15:53	N	Double Read
					VISIT 7	27JUL2016	16:37	N	Double Read
					VISIT 8	26JUL2017	15:50	N	Double Read
					VISIT 11	19AUG2020	15:54	N	Double Read
Normal lordotic LS	5_S		General		Baseline	11MAY2015	16:15	Y	Double Read
					VISIT 3A	10AUG2015	15:44	Y	Double Read
					VISIT 4	22SEP2015	16:13	Y	Double Read
					VISIT 6	08FEB2016	15:53	Y	Double Read
					VISIT 7	27JUL2016	16:37	Y	Double Read
					VISIT 8	26JUL2017	15:50	Y	Double Read
					VISIT 11	19AUG2020	15:54	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	11MAY2015	16:15	0	Double Read
					VISIT 3A	10AUG2015	15:44	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	22SEP2015	16:13	0	Double Read
					VISIT 6	08FEB2016	15:53	0	Double Read
					VISIT 7	27JUL2016	16:37	0	Double Read
					VISIT 8	26JUL2017	15:50	2	Double Read
					VISIT 11	19AUG2020	15:54	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	16:15	0	Double Read
					VISIT 3A	10AUG2015	15:44	0	Double Read
					VISIT 4	22SEP2015	16:13	0	Double Read
					VISIT 6	08FEB2016	15:53	0	Double Read
					VISIT 7	27JUL2016	16:37	0	Double Read
					VISIT 8	26JUL2017	15:50	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 11	19AUG2020	15:54	0	Double Read
					Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
					Baseline	11MAY2015	16:15	N	Double Read
					VISIT 3A	10AUG2015	15:44	N	Double Read
					VISIT 4	22SEP2015	16:13	N	Double Read
					VISIT 6	08FEB2016	15:53	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	27JUL2016	16:37	N	Double Read
					VISIT 8	26JUL2017	15:50	N	Double Read
					VISIT 11	19AUG2020	15:54	N	Double Read
					Baseline	11MAY2015	16:15	N	Double Read
					VISIT 3A	10AUG2015	15:44	N	Double Read
					VISIT 4	22SEP2015	16:13	N	Double Read
					VISIT 6	08FEB2016	15:53	N	Double Read
					VISIT 7	27JUL2016	16:37	N	Double Read
					VISIT 8	26JUL2017	15:50	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	26JUL2017	15:50	N	Double Read
					VISIT 11	19AUG2020	15:54	N	Double Read
Relevant scoliosis	5_S		General		Baseline	11MAY2015	16:15	N	Double Read
					VISIT 3A	10AUG2015	15:44	N	Double Read
					VISIT 4	22SEP2015	16:13	N	Double Read
					VISIT 6	08FEB2016	15:53	N	Double Read
					VISIT 7	27JUL2016	16:37	N	Double Read
					VISIT 8	26JUL2017	15:50	N	Double Read
					VISIT 11	19AUG2020	15:54	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	11MAY2015	16:15	N	Double Read
					VISIT 3A	10AUG2015	15:44	N	Double Read
					VISIT 4	22SEP2015	16:13	N	Double Read
					VISIT 6	08FEB2016	15:53	N	Double Read
					VISIT 7	27JUL2016	16:37	N	Double Read
					VISIT 8	26JUL2017	15:50	N	Double Read
					VISIT 11	19AUG2020	15:54	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	16:15	N	Double Read
					VISIT 3A	10AUG2015	15:44	N	Double Read
					VISIT 4	22SEP2015	16:13	N	Double Read
					VISIT 6	08FEB2016	15:53	N	Double Read
					VISIT 7	27JUL2016	16:37	N	Double Read
					VISIT 8	26JUL2017	15:50	N	Double Read
					VISIT 11	19AUG2020	15:54	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11MAY2015	16:15	65.95968	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	10AUG2015	15:44	67.73072	Double Read
					VISIT 4	22SEP2015	16:13	69.79184	Double Read
					VISIT 6	08FEB2016	15:53	65.99728	Double Read
					VISIT 7	27JUL2016	16:37	72.04032	Double Read
					VISIT 8	26JUL2017	15:50	66.64704	Double Read
					VISIT 11	19AUG2020	15:54	51.541856	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 11	19AUG2020	15:54		Double Read
					Baseline	11MAY2015	16:15	68.9856	Double Read
					VISIT 3A	10AUG2015	15:44	71.89504	Double Read
					VISIT 4	22SEP2015	16:13	69.1528	Double Read
					VISIT 6	08FEB2016	15:53	70.81296	Double Read
					VISIT 7	27JUL2016	16:37	68.9752	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	26JUL2017	15:50	65.6168	Double Read
					VISIT 11	19AUG2020	15:54	67.87616	Double Read
					Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 8	26JUL2017	15:50		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	19AUG2020	15:54		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	11MAY2015	16:15	lower	Double Read
					VISIT 3A	10AUG2015	15:44	lower	Double Read
					VISIT 4	22SEP2015	16:13	lower	Double Read
					VISIT 6	08FEB2016	15:53	lower	Double Read
					VISIT 7	27JUL2016	16:37	lower	Double Read
					VISIT 8	26JUL2017	15:50	lower	Double Read
					VISIT 11	19AUG2020	15:54	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11MAY2015	16:15	8.15032444369	Double Read
					VISIT 3A	10AUG2015	15:44	7.55902836759	Double Read
					VISIT 4	22SEP2015	16:13	7.80411754714	Double Read
					VISIT 6	08FEB2016	15:53	5.12814676405	Double Read
					VISIT 7	27JUL2016	16:37	7.37886869373	Double Read
					VISIT 8	26JUL2017	15:50	6.30391031085	Double Read
					VISIT 11	19AUG2020	15:54	5.39202310175	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11MAY2015	16:15	11.074306098	Double Read
					VISIT 3A	10AUG2015	15:44	5.6395447596	Double Read
					VISIT 4	22SEP2015	16:13	11.669780873	Double Read
					VISIT 6	08FEB2016	15:53	10.588299643	Double Read
					VISIT 7	27JUL2016	16:37	3.7095430609	Double Read
					VISIT 8	26JUL2017	15:50	5.3062816375	Double Read
					VISIT 11	19AUG2020	15:54	3.3540818753	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11MAY2015	16:15	12224.0	Double Read
					VISIT 3A	10AUG2015	15:44	11970.5	Double Read
					VISIT 4	22SEP2015	16:13	10843.5	Double Read
					VISIT 6	08FEB2016	15:53	12602.0	Double Read
					VISIT 7	27JUL2016	16:37	12291.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	26JUL2017	15:50	11171.5	Double Read
					VISIT 11	19AUG2020	15:54	13528.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read
					VISIT 11	19AUG2020	15:54		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11MAY2015	16:15	15600.5	Double Read
					VISIT 3A	10AUG2015	15:44	14550.5	Double Read
					VISIT 4	22SEP2015	16:13	14887.5	Double Read
					VISIT 6	08FEB2016	15:53	15416.5	Double Read
					VISIT 7	27JUL2016	16:37	15732.0	Double Read
					VISIT 8	26JUL2017	15:50	14150.5	Double Read
					VISIT 11	19AUG2020	15:54	15240.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	11MAY2015	16:15		Double Read
					VISIT 3A	10AUG2015	15:44		Double Read
					VISIT 4	22SEP2015	16:13		Double Read
					VISIT 6	08FEB2016	15:53		Double Read
					VISIT 7	27JUL2016	16:37		Double Read
					VISIT 8	26JUL2017	15:50		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0140 Age=49 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	19AUG2020	15:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0141 Age=27 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	21MAY2015	17:18	3	Double Read
					VISIT 4	13JUL2015	15:45	3	Double Read
					VISIT 6	11NOV2015	16:18	3	Double Read
					VISIT 7	18MAY2016	16:51	3	Double Read
					VISIT 8	-	15:56	3	Double Read
					VISIT 11	-	16:01	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	21MAY2015	17:18	3	Double Read
					VISIT 4	13JUL2015	15:45	2	Double Read
					VISIT 6	11NOV2015	16:18	3	Double Read
					VISIT 7	18MAY2016	16:51	3	Double Read
					VISIT 8	-	15:56	3	Double Read
					VISIT 11	-	16:01	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	21MAY2015	17:18	3	Double Read
					VISIT 4	13JUL2015	15:45	2	Double Read
					VISIT 6	11NOV2015	16:18	3	Double Read
					VISIT 7	18MAY2016	16:51	3	Double Read
					VISIT 8	-	15:56	3	Double Read
					VISIT 11	-	16:01	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read
					VISIT 11	-	16:01	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0141 Age=27 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 11	-	16:01	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read
					VISIT 11	-	16:01	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read
					VISIT 11	-	16:01	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	21MAY2015	17:18	Y	Double Read
					VISIT 4	13JUL2015	15:45	Y	Double Read
					VISIT 6	11NOV2015	16:18	Y	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read
					VISIT 11	-	16:01	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	21MAY2015	17:18	Y	Double Read
					VISIT 4	13JUL2015	15:45	Y	Double Read
					VISIT 6	11NOV2015	16:18	Y	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	Y	Double Read
					VISIT 11	-	16:01	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0141 Age=27 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	4_5		General		VISIT 11	-	16:01	N	Double Read
Fracture	4_5		General		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read
					VISIT 11	-	16:01	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	21MAY2015	17:18	8.895	Double Read
					VISIT 4	13JUL2015	15:45	9.755	Double Read
					VISIT 6	11NOV2015	16:18	9.745	Double Read
					VISIT 7	18MAY2016	16:51	9.2	Double Read
					VISIT 8	-	15:56	10.335	Double Read
					VISIT 11	-	16:01	10.575	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	21MAY2015	17:18	11.395	Double Read
					VISIT 4	13JUL2015	15:45	9.27	Double Read
					VISIT 6	11NOV2015	16:18	9.79	Double Read
					VISIT 7	18MAY2016	16:51	8.945	Double Read
					VISIT 8	-	15:56	9.99	Double Read
					VISIT 11	-	16:01	11.805	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	21MAY2015	17:18	10.495	Double Read
					VISIT 4	13JUL2015	15:45	10.16	Double Read
					VISIT 6	11NOV2015	16:18	10.75	Double Read
					VISIT 7	18MAY2016	16:51	10.48	Double Read
					VISIT 8	-	15:56	10.81	Double Read
					VISIT 11	-	16:01	11.47	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	21MAY2015	17:18	6.112015	Double Read
					VISIT 4	13JUL2015	15:45	6.327835	Double Read
					VISIT 6	11NOV2015	16:18	6.24122	Double Read
					VISIT 7	18MAY2016	16:51	6.102215	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0141 Age=27 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	VISIT 8	-	15:56	7.54526	Double Read
					VISIT 11	-	16:01	7.29828	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	21MAY2015	17:18	7.269805	Double Read
					VISIT 4	13JUL2015	15:45	6.529295	Double Read
					VISIT 6	11NOV2015	16:18	5.595915	Double Read
					VISIT 7	18MAY2016	16:51	5.507815	Double Read
					VISIT 8	-	15:56	6.185215	Double Read
					VISIT 11	-	16:01	7.098575	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	21MAY2015	17:18	8.114745	Double Read
					VISIT 4	13JUL2015	15:45	7.74993	Double Read
					VISIT 6	11NOV2015	16:18	7.267495	Double Read
					VISIT 7	18MAY2016	16:51	7.50916	Double Read
					VISIT 8	-	15:56	7.995725	Double Read
					VISIT 11	-	16:01	8.9523	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read
					VISIT 11	-	16:01	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read
					VISIT 11	-	16:01	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0141 Age=27 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read
					VISIT 11	-	16:01	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read
					VISIT 11	-	16:01	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read
					VISIT 11	-	16:01	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read
					VISIT 11	-	16:01	N	Double Read
Normal lordotic LS	4_5		General		Baseline	21MAY2015	17:18	Y	Double Read
					VISIT 4	13JUL2015	15:45	Y	Double Read
					VISIT 6	11NOV2015	16:18	Y	Double Read
					VISIT 7	18MAY2016	16:51	Y	Double Read
					VISIT 8	-	15:56	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0141 Age=27 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	4_5		General		VISIT 11	-	16:01	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	21MAY2015	17:18	0	Double Read
					VISIT 4	13JUL2015	15:45	0	Double Read
					VISIT 6	11NOV2015	16:18	0	Double Read
					VISIT 7	18MAY2016	16:51	0	Double Read
					VISIT 8	-	15:56	0	Double Read
					VISIT 11	-	16:01	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	21MAY2015	17:18	2	Double Read
					VISIT 4	13JUL2015	15:45	2	Double Read
					VISIT 6	11NOV2015	16:18	1	Double Read
					VISIT 7	18MAY2016	16:51	0	Double Read
					VISIT 8	-	15:56	2	Double Read
					VISIT 11	-	16:01	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	21MAY2015	17:18	0	Double Read
					VISIT 4	13JUL2015	15:45	0	Double Read
					VISIT 6	11NOV2015	16:18	0	Double Read
					VISIT 7	18MAY2016	16:51	0	Double Read
					VISIT 8	-	15:56	0	Double Read
					VISIT 11	-	16:01	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read
					VISIT 11	-	16:01	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0141 Age=27 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 11	-	16:01	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read
					VISIT 11	-	16:01	N	Double Read
Relevant scoliosis	4_5		General		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read
					VISIT 11	-	16:01	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read
					VISIT 11	-	16:01	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read
					VISIT 8	-	15:56	N	Double Read
					VISIT 11	-	16:01	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	21MAY2015	17:18	N	Double Read
					VISIT 4	13JUL2015	15:45	N	Double Read
					VISIT 6	11NOV2015	16:18	N	Double Read
					VISIT 7	18MAY2016	16:51	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0141 Age=27 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	-	15:56	N	Double Read
					VISIT 11	-	16:01	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	21MAY2015	17:18	80.43712	Double Read
					VISIT 4	13JUL2015	15:45	67.71728	Double Read
					VISIT 6	11NOV2015	16:18	66.49856	Double Read
					VISIT 7	18MAY2016	16:51	81.676	Double Read
					VISIT 8	-	15:56	76.0248	Double Read
					VISIT 11	-	16:01	77.75872	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	21MAY2015	17:18	69.85248	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0141 Age=27 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 4	13JUL2015	15:45	80.45392	Double Read
					VISIT 6	11NOV2015	16:18	87.90208	Double Read
					VISIT 7	18MAY2016	16:51	77.4472	Double Read
					VISIT 8	-	15:56	74.90848	Double Read
					VISIT 11	-	16:01	69.12352	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	21MAY2015	17:18	82.69264	Double Read
					VISIT 4	13JUL2015	15:45	82.91008	Double Read
					VISIT 6	11NOV2015	16:18	77.68208	Double Read
					VISIT 7	18MAY2016	16:51	80.01792	Double Read
					VISIT 8	-	15:56	74.59264	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	-	16:01	74.82768	Double Read
					Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0141 Age=27 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0141 Age=27 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	21MAY2015	17:18	equal	Double Read
					VISIT 4	13JUL2015	15:45	higher	Double Read
					VISIT 6	11NOV2015	16:18	higher	Double Read
					VISIT 7	18MAY2016	16:51	higher	Double Read
					VISIT 8	-	15:56	equal	Double Read
					VISIT 11	-	16:01	equal	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	21MAY2015	17:18	lower	Double Read
					VISIT 4	13JUL2015	15:45	equal	Double Read
					VISIT 6	11NOV2015	16:18	higher	Double Read
					VISIT 7	18MAY2016	16:51	equal	Double Read
					VISIT 8	-	15:56	equal	Double Read
					VISIT 11	-	16:01	equal	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0141 Age=27 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0141 Age=27 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	21MAY2015	17:18	6.56814676407	Double Read
					VISIT 4	13JUL2015	15:45	11.7069882792	Double Read
					VISIT 6	11NOV2015	16:18	9.24069984712	Double Read
					VISIT 7	18MAY2016	16:51	6.96449804654	Double Read
					VISIT 8	-	15:56	9.05951418379	Double Read
					VISIT 11	-	16:01	9.96546288432	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	21MAY2015	17:18	10.4184338372	Double Read
					VISIT 4	13JUL2015	15:45	6.74933242738	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0141 Age=27 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 6	11NOV2015	16:18	4.17384066587	Double Read
					VISIT 7	18MAY2016	16:51	7.47409546458	Double Read
					VISIT 8	-	15:56	5.46967895363	Double Read
					VISIT 11	-	16:01	11.3761236623	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	21MAY2015	17:18	4.09942585358	Double Read
					VISIT 4	13JUL2015	15:45	8.52968914557	Double Read
					VISIT 6	11NOV2015	16:18	12.6889757092	Double Read
					VISIT 7	18MAY2016	16:51	12.329403771	Double Read
					VISIT 8	-	15:56	6.79463224053	Double Read
					VISIT 11	-	16:01	10.795916426	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	21MAY2015	17:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0141 Age=27 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	21MAY2015	17:18	7892.0	Double Read
					VISIT 4	13JUL2015	15:45	7844.5	Double Read
					VISIT 6	11NOV2015	16:18	7238.0	Double Read
					VISIT 7	18MAY2016	16:51	7254.0	Double Read
					VISIT 8	-	15:56	7058.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0141 Age=27 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	21MAY2015	17:18	11441.0	Double Read
					VISIT 4	13JUL2015	15:45	8428.0	Double Read
					VISIT 6	11NOV2015	16:18	9087.0	Double Read
					VISIT 7	18MAY2016	16:51	8007.5	Double Read
					VISIT 8	-	15:56	8383.0	Double Read
					VISIT 11	-	16:01	10552.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	21MAY2015	17:18	11179.5	Double Read
					VISIT 4	13JUL2015	15:45	11446.0	Double Read
					VISIT 6	11NOV2015	16:18	10942.0	Double Read
					VISIT 7	18MAY2016	16:51	10517.0	Double Read
					VISIT 8	-	15:56	10096.5	Double Read
					VISIT 11	-	16:01	11778.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	21MAY2015	17:18		Double Read
					VISIT 4	13JUL2015	15:45		Double Read
					VISIT 6	11NOV2015	16:18		Double Read
					VISIT 7	18MAY2016	16:51		Double Read
					VISIT 8	-	15:56		Double Read
					VISIT 11	-	16:01		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0141 Age=27 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	-	16:01		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	26MAY2015	16:53	3	Double Read
					VISIT 3A	24AUG2015	16:06	3	Double Read
					VISIT 4	05OCT2015	16:33	4	Double Read
					VISIT 6	02MAR2016	17:14	3	Double Read
					VISIT 7	31AUG2016	15:59	4	Double Read
					VISIT 8	30AUG2017	17:03	3	Double Read
					VISIT 11	05AUG2020	16:04	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	26MAY2015	16:53	3	Double Read
					VISIT 3A	24AUG2015	16:06	3	Double Read
					VISIT 4	05OCT2015	16:33	4	Double Read
					VISIT 6	02MAR2016	17:14	3	Double Read
					VISIT 7	31AUG2016	15:59	4	Double Read
					VISIT 8	30AUG2017	17:03	4	Double Read
					VISIT 11	05AUG2020	16:04	4	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	26MAY2015	16:53	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	24AUG2015	16:06	N	Double Read
					VISIT 4	05OCT2015	16:33	N	Double Read
					VISIT 6	02MAR2016	17:14	N	Double Read
					VISIT 7	31AUG2016	15:59	N	Double Read
					VISIT 8	30AUG2017	17:03	N	Double Read
					VISIT 11	05AUG2020	16:04	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	26MAY2015	16:53	N	Double Read
					VISIT 3A	24AUG2015	16:06	N	Double Read
					VISIT 4	05OCT2015	16:33	N	Double Read
					VISIT 6	02MAR2016	17:14	N	Double Read
					VISIT 7	31AUG2016	15:59	N	Double Read
					VISIT 8	30AUG2017	17:03	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	05AUG2020	16:04	N	Double Read
					Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
					Baseline	26MAY2015	16:53	Y	Double Read
					VISIT 3A	24AUG2015	16:06	Y	Double Read
					VISIT 4	05OCT2015	16:33	Y	Double Read
					VISIT 6	02MAR2016	17:14	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	31AUG2016	15:59	N	Double Read
					VISIT 8	30AUG2017	17:03	Y	Double Read
					VISIT 11	05AUG2020	16:04	Y	Double Read
					Baseline	26MAY2015	16:53	N	Double Read
					VISIT 3A	24AUG2015	16:06	N	Double Read
					VISIT 4	05OCT2015	16:33	N	Double Read
					VISIT 6	02MAR2016	17:14	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	31AUG2016	15:59	N	Double Read
					VISIT 8	30AUG2017	17:03	N	Double Read
					VISIT 11	05AUG2020	16:04	Y	Double Read
Extradiscal fluid collection	5_S		General		Baseline	26MAY2015	16:53	N	Double Read
					VISIT 3A	24AUG2015	16:06	N	Double Read
					VISIT 4	05OCT2015	16:33	N	Double Read
					VISIT 6	02MAR2016	17:14	N	Double Read
					VISIT 7	31AUG2016	15:59	N	Double Read
					VISIT 8	30AUG2017	17:03	N	Double Read
					VISIT 11	05AUG2020	16:04	N	Double Read
Fracture	5_S		General		Baseline	26MAY2015	16:53	N	Double Read
					VISIT 3A	24AUG2015	16:06	N	Double Read
					VISIT 4	05OCT2015	16:33	N	Double Read
					VISIT 6	02MAR2016	17:14	N	Double Read
					VISIT 7	31AUG2016	15:59	N	Double Read
					VISIT 8	30AUG2017	17:03	N	Double Read
					VISIT 11	05AUG2020	16:04	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	26MAY2015	16:53	12.355	Double Read
					VISIT 3A	24AUG2015	16:06	14.015	Double Read
					VISIT 4	05OCT2015	16:33	11.2	Double Read
					VISIT 6	02MAR2016	17:14	13.155	Double Read
					VISIT 7	31AUG2016	15:59	14.015	Double Read
					VISIT 8	30AUG2017	17:03	13.895	Double Read
					VISIT 11	05AUG2020	16:04	12.695	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	26MAY2015	16:53	11.26	Double Read
					VISIT 3A	24AUG2015	16:06	10.85	Double Read
					VISIT 4	05OCT2015	16:33	9.665	Double Read
					VISIT 6	02MAR2016	17:14	11.875	Double Read
					VISIT 7	31AUG2016	15:59	10.74	Double Read
					VISIT 8	30AUG2017	17:03	11.205	Double Read
					VISIT 11	05AUG2020	16:04	9.085	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	26MAY2015	16:53	7.788505	Double Read
					VISIT 3A	24AUG2015	16:06	8.288135	Double Read
					VISIT 4	05OCT2015	16:33	7.93688	Double Read
					VISIT 6	02MAR2016	17:14	7.79016	Double Read
					VISIT 7	31AUG2016	15:59	7.93092	Double Read
					VISIT 8	30AUG2017	17:03	8.039665	Double Read
					VISIT 11	05AUG2020	16:04	7.395735	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	26MAY2015	16:53	9.15137	Double Read
					VISIT 3A	24AUG2015	16:06	9.010955	Double Read
					VISIT 4	05OCT2015	16:33	8.5463	Double Read
					VISIT 6	02MAR2016	17:14	8.996095	Double Read
					VISIT 7	31AUG2016	15:59	7.97976	Double Read
					VISIT 8	30AUG2017	17:03	8.472525	Double Read
					VISIT 11	05AUG2020	16:04	7.45436	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	26MAY2015	16:53	N	Double Read
					VISIT 3A	24AUG2015	16:06	N	Double Read
					VISIT 4	05OCT2015	16:33	N	Double Read
					VISIT 6	02MAR2016	17:14	N	Double Read
					VISIT 7	31AUG2016	15:59	N	Double Read
					VISIT 8	30AUG2017	17:03	N	Double Read
					VISIT 11	05AUG2020	16:04	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	26MAY2015	16:53	N	Double Read
					VISIT 3A	24AUG2015	16:06	N	Double Read
					VISIT 4	05OCT2015	16:33	N	Double Read
					VISIT 6	02MAR2016	17:14	N	Double Read
					VISIT 7	31AUG2016	15:59	N	Double Read
					VISIT 8	30AUG2017	17:03	N	Double Read
					VISIT 11	05AUG2020	16:04	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	26MAY2015	16:53	N	Double Read
					VISIT 3A	24AUG2015	16:06	N	Double Read
					VISIT 4	05OCT2015	16:33	N	Double Read
					VISIT 6	02MAR2016	17:14	N	Double Read
					VISIT 7	31AUG2016	15:59	N	Double Read
					VISIT 8	30AUG2017	17:03	N	Double Read
					VISIT 11	05AUG2020	16:04	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	26MAY2015	16:53	N	Double Read
					VISIT 3A	24AUG2015	16:06	N	Double Read
					VISIT 4	05OCT2015	16:33	N	Double Read
					VISIT 6	02MAR2016	17:14	N	Double Read
					VISIT 7	31AUG2016	15:59	N	Double Read
					VISIT 8	30AUG2017	17:03	N	Double Read
					VISIT 11	05AUG2020	16:04	N	Double Read
Normal lordotic LS	5_S		General		Baseline	26MAY2015	16:53	Y	Double Read
					VISIT 3A	24AUG2015	16:06	Y	Double Read
					VISIT 4	05OCT2015	16:33	Y	Double Read
					VISIT 6	02MAR2016	17:14	Y	Double Read
					VISIT 7	31AUG2016	15:59	Y	Double Read
					VISIT 8	30AUG2017	17:03	Y	Double Read
					VISIT 11	05AUG2020	16:04	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	26MAY2015	16:53	0	Double Read
					VISIT 3A	24AUG2015	16:06	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	05OCT2015	16:33	0	Double Read
					VISIT 6	02MAR2016	17:14	0	Double Read
					VISIT 7	31AUG2016	15:59	0	Double Read
					VISIT 8	30AUG2017	17:03	0	Double Read
					VISIT 11	05AUG2020	16:04	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	26MAY2015	16:53	2	Double Read
					VISIT 3A	24AUG2015	16:06	2	Double Read
					VISIT 4	05OCT2015	16:33	2	Double Read
					VISIT 6	02MAR2016	17:14	1	Double Read
					VISIT 7	31AUG2016	15:59	1	Double Read
					VISIT 8	30AUG2017	17:03	2	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 11	05AUG2020	16:04	2	Double Read
					Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
					Baseline	26MAY2015	16:53	N	Double Read
					VISIT 3A	24AUG2015	16:06	N	Double Read
					VISIT 4	05OCT2015	16:33	N	Double Read
					VISIT 6	02MAR2016	17:14	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	31AUG2016	15:59	N	Double Read
					VISIT 8	30AUG2017	17:03	N	Double Read
					VISIT 11	05AUG2020	16:04	N	Double Read
					Baseline	26MAY2015	16:53	N	Double Read
					VISIT 3A	24AUG2015	16:06	N	Double Read
					VISIT 4	05OCT2015	16:33	N	Double Read
					VISIT 6	02MAR2016	17:14	N	Double Read
					VISIT 7	31AUG2016	15:59	N	Double Read
					VISIT 8	30AUG2017	17:03	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	30AUG2017	17:03	N	Double Read
					VISIT 11	05AUG2020	16:04	N	Double Read
Relevant scoliosis	5_S		General		Baseline	26MAY2015	16:53	N	Double Read
					VISIT 3A	24AUG2015	16:06	N	Double Read
					VISIT 4	05OCT2015	16:33	N	Double Read
					VISIT 6	02MAR2016	17:14	N	Double Read
					VISIT 7	31AUG2016	15:59	N	Double Read
					VISIT 8	30AUG2017	17:03	N	Double Read
					VISIT 11	05AUG2020	16:04	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	26MAY2015	16:53	N	Double Read
					VISIT 3A	24AUG2015	16:06	N	Double Read
					VISIT 4	05OCT2015	16:33	N	Double Read
					VISIT 6	02MAR2016	17:14	N	Double Read
					VISIT 7	31AUG2016	15:59	N	Double Read
					VISIT 8	30AUG2017	17:03	N	Double Read
					VISIT 11	05AUG2020	16:04	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	26MAY2015	16:53	N	Double Read
					VISIT 3A	24AUG2015	16:06	N	Double Read
					VISIT 4	05OCT2015	16:33	N	Double Read
					VISIT 6	02MAR2016	17:14	N	Double Read
					VISIT 7	31AUG2016	15:59	N	Double Read
					VISIT 8	30AUG2017	17:03	N	Double Read
					VISIT 11	05AUG2020	16:04	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	26MAY2015	16:53	70.33824	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	24AUG2015	16:06	67.57136	Double Read
					VISIT 4	05OCT2015	16:33	71.3008	Double Read
					VISIT 6	02MAR2016	17:14	72.36416	Double Read
					VISIT 7	31AUG2016	15:59	72.43616	Double Read
					VISIT 8	30AUG2017	17:03	70.65392	Double Read
					VISIT 11	05AUG2020	16:04	70.30528	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 11	05AUG2020	16:04		Double Read
					Baseline	26MAY2015	16:53	66.02784	Double Read
					VISIT 3A	24AUG2015	16:06	65.58016	Double Read
					VISIT 4	05OCT2015	16:33	67.58384	Double Read
					VISIT 6	02MAR2016	17:14	68.43152	Double Read
					VISIT 7	31AUG2016	15:59	68.34816	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	30AUG2017	17:03	73.684	Double Read
					VISIT 11	05AUG2020	16:04	64.33712	Double Read
					VISIT 3A	24AUG2015	16:06		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	05AUG2020	16:04		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	26MAY2015	16:53	equal	Double Read
					VISIT 3A	24AUG2015	16:06	equal	Double Read
					VISIT 4	05OCT2015	16:33	higher	Double Read
					VISIT 6	02MAR2016	17:14	equal	Double Read
					VISIT 7	31AUG2016	15:59	equal	Double Read
					VISIT 8	30AUG2017	17:03	higher	Double Read
					VISIT 11	05AUG2020	16:04	higher	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	26MAY2015	16:53	8.6631561066	Double Read
					VISIT 3A	24AUG2015	16:06	9.8239035162	Double Read
					VISIT 4	05OCT2015	16:33	9.2859928656	Double Read
					VISIT 6	02MAR2016	17:14	6.4415152029	Double Read
					VISIT 7	31AUG2016	15:59	9.5124851367	Double Read
					VISIT 8	30AUG2017	17:03	9.8725394938	Double Read
					VISIT 11	05AUG2020	16:04	7.4740954645	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	26MAY2015	16:53	8.7650755902	Double Read
					VISIT 3A	24AUG2015	16:06	5.4357057924	Double Read
					VISIT 4	05OCT2015	16:33	7.0664175301	Double Read
					VISIT 6	02MAR2016	17:14	7.2738916256	Double Read
					VISIT 7	31AUG2016	15:59	9.5172074061	Double Read
					VISIT 8	30AUG2017	17:03	8.0969390181	Double Read
					VISIT 11	05AUG2020	16:04	6.2001019194	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	26MAY2015	16:53	9985.5	Double Read
					VISIT 3A	24AUG2015	16:06	10631.0	Double Read
					VISIT 4	05OCT2015	16:33	9029.0	Double Read
					VISIT 6	02MAR2016	17:14	10647.5	Double Read
					VISIT 7	31AUG2016	15:59	10512.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	30AUG2017	17:03	10881.5	Double Read
					VISIT 11	05AUG2020	16:04	9571.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read
					VISIT 11	05AUG2020	16:04		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	26MAY2015	16:53	10864.5	Double Read
					VISIT 3A	24AUG2015	16:06	11406.0	Double Read
					VISIT 4	05OCT2015	16:33	9437.5	Double Read
					VISIT 6	02MAR2016	17:14	11745.0	Double Read
					VISIT 7	31AUG2016	15:59	12238.0	Double Read
					VISIT 8	30AUG2017	17:03	11139.0	Double Read
					VISIT 11	05AUG2020	16:04	8745.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	26MAY2015	16:53		Double Read
					VISIT 3A	24AUG2015	16:06		Double Read
					VISIT 4	05OCT2015	16:33		Double Read
					VISIT 6	02MAR2016	17:14		Double Read
					VISIT 7	31AUG2016	15:59		Double Read
					VISIT 8	30AUG2017	17:03		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0142 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	05AUG2020	16:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	16JUN2015	15:57	3	Double Read
					VISIT 3A	21SEP2015	15:26	3	Double Read
					VISIT 4	02NOV2015	15:56	3	Double Read
					VISIT 6	09MAR2016	16:22	3	Double Read
					VISIT 7	07SEP2016	15:44	3	Double Read
					VISIT 8	23AUG2017	15:48	3	Double Read
					VISIT 11	16SEP2020	16:30	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	16JUN2015	15:57	3	Double Read
					VISIT 3A	21SEP2015	15:26	3	Double Read
					VISIT 4	02NOV2015	15:56	2	Double Read
					VISIT 6	09MAR2016	16:22	2	Double Read
					VISIT 7	07SEP2016	15:44	2	Double Read
					VISIT 8	23AUG2017	15:48	3	Double Read
					VISIT 11	16SEP2020	16:30	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	16JUN2015	15:57	3	Double Read
					VISIT 3A	21SEP2015	15:26	1	Double Read
					VISIT 4	02NOV2015	15:56	3	Double Read
					VISIT 6	09MAR2016	16:22	3	Double Read
					VISIT 7	07SEP2016	15:44	3	Double Read
					VISIT 8	23AUG2017	15:48	3	Double Read
					VISIT 11	16SEP2020	16:30	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	16JUN2015	15:57	N	Double Read
					VISIT 3A	21SEP2015	15:26	N	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read
					VISIT 7	07SEP2016	15:44	N	Double Read
					VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	16JUN2015	15:57	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 3A	21SEP2015	15:26	N	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read
					VISIT 7	07SEP2016	15:44	N	Double Read
					VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	16JUN2015	15:57	N	Double Read
					VISIT 3A	21SEP2015	15:26	N	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read
					VISIT 7	07SEP2016	15:44	N	Double Read
					VISIT 8	23AUG2017	15:48	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 11	16SEP2020	16:30	N	Double Read
					Baseline	16JUN2015	15:57	N	Double Read
					VISIT 3A	21SEP2015	15:26	Y	Double Read
					VISIT 4	02NOV2015	15:56	Y	Double Read
					VISIT 6	09MAR2016	16:22	Y	Double Read
					VISIT 7	07SEP2016	15:44	Y	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read
					Baseline	16JUN2015	15:57	Y	Double Read
					VISIT 3A	21SEP2015	15:26	Y	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	07SEP2016	15:44	N	Double Read
					VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read
					Baseline	16JUN2015	15:57	N	Double Read
					VISIT 3A	21SEP2015	15:26	N	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	07SEP2016	15:44	N	Double Read
					VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	16JUN2015	15:57	N	Double Read
					VISIT 3A	21SEP2015	15:26	N	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read
					VISIT 7	07SEP2016	15:44	N	Double Read
					VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read
Fracture	4_5		General		Baseline	16JUN2015	15:57	N	Double Read
					VISIT 3A	21SEP2015	15:26	N	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read
					VISIT 7	07SEP2016	15:44	N	Double Read
					VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	16JUN2015	15:57	11.125	Double Read
					VISIT 3A	21SEP2015	15:26	11.91	Double Read
					VISIT 4	02NOV2015	15:56	11.67	Double Read
					VISIT 6	09MAR2016	16:22	12.225	Double Read
					VISIT 7	07SEP2016	15:44	12.13	Double Read
					VISIT 8	23AUG2017	15:48	12.525	Double Read
					VISIT 11	16SEP2020	16:30	10.005	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	16JUN2015	15:57	10.72	Double Read
					VISIT 3A	21SEP2015	15:26	10.6	Double Read
					VISIT 4	02NOV2015	15:56	11.21	Double Read
					VISIT 6	09MAR2016	16:22	10.72	Double Read
					VISIT 7	07SEP2016	15:44	11.1	Double Read
					VISIT 8	23AUG2017	15:48	10.76	Double Read
					VISIT 11	16SEP2020	16:30	10.94	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	16JUN2015	15:57	12.275	Double Read
					VISIT 3A	21SEP2015	15:26	12.83	Double Read
					VISIT 4	02NOV2015	15:56	13.195	Double Read
					VISIT 6	09MAR2016	16:22	12.65	Double Read
					VISIT 7	07SEP2016	15:44	13.01	Double Read
					VISIT 8	23AUG2017	15:48	12.555	Double Read
					VISIT 11	16SEP2020	16:30	13.385	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	16JUN2015	15:57	6.70565	Double Read
					VISIT 3A	21SEP2015	15:26	7.96553	Double Read
					VISIT 4	02NOV2015	15:56	7.2297	Double Read
					VISIT 6	09MAR2016	16:22	9.01806	Double Read
					VISIT 7	07SEP2016	15:44	7.24519	Double Read
					VISIT 8	23AUG2017	15:48	8.19056	Double Read
					VISIT 11	16SEP2020	16:30	4.75044	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	16JUN2015	15:57	9.23493	Double Read
					VISIT 3A	21SEP2015	15:26	9.16644	Double Read
					VISIT 4	02NOV2015	15:56	9.315715	Double Read
					VISIT 6	09MAR2016	16:22	8.427875	Double Read
					VISIT 7	07SEP2016	15:44	8.631445	Double Read
					VISIT 8	23AUG2017	15:48	8.530415	Double Read
					VISIT 11	16SEP2020	16:30	7.797695	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	16JUN2015	15:57	13.05975	Double Read
					VISIT 3A	21SEP2015	15:26	11.49565	Double Read
					VISIT 4	02NOV2015	15:56	11.7621	Double Read
					VISIT 6	09MAR2016	16:22	10.56605	Double Read
					VISIT 7	07SEP2016	15:44	11.6973	Double Read
					VISIT 8	23AUG2017	15:48	11.8556	Double Read
					VISIT 11	16SEP2020	16:30	11.8235	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	16JUN2015	15:57	N	Double Read
					VISIT 3A	21SEP2015	15:26	N	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read
					VISIT 7	07SEP2016	15:44	N	Double Read
					VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	16JUN2015	15:57	N	Double Read
					VISIT 3A	21SEP2015	15:26	N	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read
					VISIT 7	07SEP2016	15:44	N	Double Read
					VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	16JUN2015	15:57	N	Double Read
					VISIT 3A	21SEP2015	15:26	N	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read
					VISIT 7	07SEP2016	15:44	N	Double Read
					VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	16JUN2015	15:57	N	Double Read
					VISIT 3A	21SEP2015	15:26	N	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read
					VISIT 7	07SEP2016	15:44	N	Double Read
					VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	16JUN2015	15:57	N	Double Read
					VISIT 3A	21SEP2015	15:26	N	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read
					VISIT 7	07SEP2016	15:44	N	Double Read
					VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	16JUN2015	15:57	N	Double Read
					VISIT 3A	21SEP2015	15:26	N	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read
					VISIT 7	07SEP2016	15:44	N	Double Read
					VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read
Normal lordotic LS	4_5		General		Baseline	16JUN2015	15:57	Y	Double Read
					VISIT 3A	21SEP2015	15:26	Y	Double Read
					VISIT 4	02NOV2015	15:56	Y	Double Read
					VISIT 6	09MAR2016	16:22	Y	Double Read
					VISIT 7	07SEP2016	15:44	Y	Double Read
					VISIT 8	23AUG2017	15:48	Y	Double Read
					VISIT 11	16SEP2020	16:30	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	16JUN2015	15:57	0	Double Read
					VISIT 3A	21SEP2015	15:26	0	Double Read
					VISIT 4	02NOV2015	15:56	0	Double Read
					VISIT 6	09MAR2016	16:22	0	Double Read
					VISIT 7	07SEP2016	15:44	0	Double Read
					VISIT 8	23AUG2017	15:48	0	Double Read
					VISIT 11	16SEP2020	16:30	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	16JUN2015	15:57	0	Double Read
					VISIT 3A	21SEP2015	15:26	2	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 4	02NOV2015	15:56	0	Double Read
					VISIT 6	09MAR2016	16:22	0	Double Read
					VISIT 7	07SEP2016	15:44	0	Double Read
					VISIT 8	23AUG2017	15:48	0	Double Read
					VISIT 11	16SEP2020	16:30	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	16JUN2015	15:57	0	Double Read
					VISIT 3A	21SEP2015	15:26	0	Double Read
					VISIT 4	02NOV2015	15:56	0	Double Read
					VISIT 6	09MAR2016	16:22	0	Double Read
					VISIT 7	07SEP2016	15:44	0	Double Read
					VISIT 8	23AUG2017	15:48	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 11	16SEP2020	16:30	0	Double Read
					Baseline	16JUN2015	15:57	N	Double Read
					VISIT 3A	21SEP2015	15:26	N	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read
					VISIT 7	07SEP2016	15:44	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read
					Baseline	16JUN2015	15:57	N	Double Read
					VISIT 3A	21SEP2015	15:26	N	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	07SEP2016	15:44	N	Double Read
					VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read
					VISIT 3A	21SEP2015	15:26	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read
Relevant scoliosis	4_5		General		Baseline	16JUN2015	15:57	N	Double Read
					VISIT 3A	21SEP2015	15:26	N	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read
					VISIT 7	07SEP2016	15:44	N	Double Read
					VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	16JUN2015	15:57	N	Double Read
					VISIT 3A	21SEP2015	15:26	N	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read
					VISIT 7	07SEP2016	15:44	N	Double Read
					VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	16JUN2015	15:57	N	Double Read
					VISIT 3A	21SEP2015	15:26	N	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read
					VISIT 7	07SEP2016	15:44	N	Double Read
					VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	16JUN2015	15:57	N	Double Read
					VISIT 3A	21SEP2015	15:26	N	Double Read
					VISIT 4	02NOV2015	15:56	N	Double Read
					VISIT 6	09MAR2016	16:22	N	Double Read
					VISIT 7	07SEP2016	15:44	N	Double Read
					VISIT 8	23AUG2017	15:48	N	Double Read
					VISIT 11	16SEP2020	16:30	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	16JUN2015	15:57	85.57424	Double Read
					VISIT 3A	21SEP2015	15:26	77.96144	Double Read
					VISIT 4	02NOV2015	15:56	77.7832	Double Read
					VISIT 6	09MAR2016	16:22	100.71616	Double Read
					VISIT 7	07SEP2016	15:44	81.42544	Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30	79.65728	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	16JUN2015	15:57	73.75232	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	21SEP2015	15:26	82.7368	Double Read
					VISIT 4	02NOV2015	15:56	80.34864	Double Read
					VISIT 6	09MAR2016	16:22	91.80448	Double Read
					VISIT 7	07SEP2016	15:44	85.85776	Double Read
					VISIT 8	23AUG2017	15:48	80.4176	Double Read
					VISIT 11	16SEP2020	16:30	72.65136	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	16JUN2015	15:57	71.73536	Double Read
					VISIT 3A	21SEP2015	15:26	69.6896	Double Read
					VISIT 4	02NOV2015	15:56	73.29856	Double Read
					VISIT 6	09MAR2016	16:22	74.50096	Double Read
					VISIT 7	07SEP2016	15:44	73.91696	Double Read
					VISIT 8	23AUG2017	15:48	74.73696	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	16SEP2020	16:30	60.3296	Double Read
					VISIT 3A	21SEP2015	15:26		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	16JUN2015	15:57	equal	Double Read
					VISIT 3A	21SEP2015	15:26	higher	Double Read
					VISIT 4	02NOV2015	15:56	higher	Double Read
					VISIT 6	09MAR2016	16:22	higher	Double Read
					VISIT 7	07SEP2016	15:44	higher	Double Read
					VISIT 8	23AUG2017	15:48	higher	Double Read
					VISIT 11	16SEP2020	16:30	equal	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 8	23AUG2017	15:48		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		VISIT 11	16SEP2020	16:30		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	16JUN2015	15:57	higher	Double Read
					VISIT 3A	21SEP2015	15:26	higher	Double Read
					VISIT 4	02NOV2015	15:56	higher	Double Read
					VISIT 6	09MAR2016	16:22	higher	Double Read
					VISIT 7	07SEP2016	15:44	higher	Double Read
					VISIT 8	23AUG2017	15:48	higher	Double Read
					VISIT 11	16SEP2020	16:30	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	16JUN2015	15:57	8.12576184816	Double Read
					VISIT 3A	21SEP2015	15:26	5.85794462375	Double Read
					VISIT 4	02NOV2015	15:56	10.8791302871	Double Read
					VISIT 6	09MAR2016	16:22	2.7320129098	Double Read
					VISIT 7	07SEP2016	15:44	4.82135552914	Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30	2.86344827587	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	16JUN2015	15:57	10.777849498	Double Read
					VISIT 3A	21SEP2015	15:26	9.2746730083	Double Read
					VISIT 4	02NOV2015	15:56	4.1081841345	Double Read
					VISIT 6	09MAR2016	16:22	8.7990487515	Double Read
					VISIT 7	07SEP2016	15:44	7.8553490742	Double Read
					VISIT 8	23AUG2017	15:48	4.2709155766	Double Read
					VISIT 11	16SEP2020	16:30	5.1469339222	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	16JUN2015	15:57	6.335593681	Double Read
					VISIT 3A	21SEP2015	15:26	10.9808799049	Double Read
					VISIT 4	02NOV2015	15:56	11.1167725497	Double Read
					VISIT 6	09MAR2016	16:22	11.1924171904	Double Read
					VISIT 7	07SEP2016	15:44	7.64758960421	Double Read
					VISIT 8	23AUG2017	15:48	11.3907185324	Double Read
					VISIT 11	16SEP2020	16:30	4.71844402922	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	16JUN2015	15:57	12048.5	Double Read
					VISIT 3A	21SEP2015	15:26	12026.0	Double Read
					VISIT 4	02NOV2015	15:56	11251.0	Double Read
					VISIT 6	09MAR2016	16:22	11274.5	Double Read
					VISIT 7	07SEP2016	15:44	12346.5	Double Read
					VISIT 8	23AUG2017	15:48	12351.0	Double Read
					VISIT 11	16SEP2020	16:30	9180.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	16JUN2015	15:57	13018.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	21SEP2015	15:26	13845.0	Double Read
					VISIT 4	02NOV2015	15:56	14190.5	Double Read
					VISIT 6	09MAR2016	16:22	12474.5	Double Read
					VISIT 7	07SEP2016	15:44	14169.0	Double Read
					VISIT 8	23AUG2017	15:48	12359.5	Double Read
					VISIT 11	16SEP2020	16:30	13525.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read
					VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	16JUN2015	15:57	17606.5	Double Read
					VISIT 3A	21SEP2015	15:26	18414.5	Double Read
					VISIT 4	02NOV2015	15:56	17769.0	Double Read
					VISIT 6	09MAR2016	16:22	17558.5	Double Read
					VISIT 7	07SEP2016	15:44	18133.5	Double Read
					VISIT 8	23AUG2017	15:48	17708.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	16JUN2015	15:57		Double Read
					VISIT 3A	21SEP2015	15:26		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0143 Age=44 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	02NOV2015	15:56		Double Read
					VISIT 6	09MAR2016	16:22		Double Read
					VISIT 7	07SEP2016	15:44		Double Read
					VISIT 8	23AUG2017	15:48		Double Read
					VISIT 11	16SEP2020	16:30		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	22JUN2015	16:11	3	Double Read
					VISIT 3A	21SEP2015	16:12	4	Double Read
					VISIT 4	03NOV2015	15:46	3	Double Read
					VISIT 6	30MAR2016	16:15	3	Double Read
					VISIT 7	21SEP2016	15:59	4	Double Read
					VISIT 8	30AUG2017	16:17	3	Double Read
					VISIT 11	09SEP2020	16:04	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22JUN2015	16:11	2	Double Read
					VISIT 3A	21SEP2015	16:12	2	Double Read
					VISIT 4	03NOV2015	15:46	2	Double Read
					VISIT 6	30MAR2016	16:15	2	Double Read
					VISIT 7	21SEP2016	15:59	2	Double Read
					VISIT 8	30AUG2017	16:17	2	Double Read
					VISIT 11	09SEP2020	16:04	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	22JUN2015	16:11	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	21SEP2015	16:12	N	Double Read
					VISIT 4	03NOV2015	15:46	N	Double Read
					VISIT 6	30MAR2016	16:15	N	Double Read
					VISIT 7	21SEP2016	15:59	N	Double Read
					VISIT 8	30AUG2017	16:17	N	Double Read
					VISIT 11	09SEP2020	16:04	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22JUN2015	16:11	N	Double Read
					VISIT 3A	21SEP2015	16:12	N	Double Read
					VISIT 4	03NOV2015	15:46	N	Double Read
					VISIT 6	30MAR2016	16:15	N	Double Read
					VISIT 7	21SEP2016	15:59	N	Double Read
					VISIT 8	30AUG2017	16:17	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	09SEP2020	16:04	N	Double Read
					Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
					Baseline	22JUN2015	16:11	Y	Double Read
					VISIT 3A	21SEP2015	16:12	Y	Double Read
					VISIT 4	03NOV2015	15:46	Y	Double Read
					VISIT 6	30MAR2016	16:15	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	21SEP2016	15:59	Y	Double Read
					VISIT 8	30AUG2017	16:17	Y	Double Read
					VISIT 11	09SEP2020	16:04	Y	Double Read
					Baseline	22JUN2015	16:11	N	Double Read
					VISIT 3A	21SEP2015	16:12	N	Double Read
					VISIT 4	03NOV2015	15:46	N	Double Read
					VISIT 6	30MAR2016	16:15	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	21SEP2016	15:59	N	Double Read
					VISIT 8	30AUG2017	16:17	N	Double Read
					VISIT 11	09SEP2020	16:04	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	22JUN2015	16:11	N	Double Read
					VISIT 3A	21SEP2015	16:12	N	Double Read
					VISIT 4	03NOV2015	15:46	N	Double Read
					VISIT 6	30MAR2016	16:15	N	Double Read
					VISIT 7	21SEP2016	15:59	N	Double Read
					VISIT 8	30AUG2017	16:17	N	Double Read
					VISIT 11	09SEP2020	16:04	N	Double Read
Fracture	5_S		General		Baseline	22JUN2015	16:11	N	Double Read
					VISIT 3A	21SEP2015	16:12	N	Double Read
					VISIT 4	03NOV2015	15:46	N	Double Read
					VISIT 6	30MAR2016	16:15	N	Double Read
					VISIT 7	21SEP2016	15:59	N	Double Read
					VISIT 8	30AUG2017	16:17	N	Double Read
					VISIT 11	09SEP2020	16:04	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22JUN2015	16:11	13.475	Double Read
					VISIT 3A	21SEP2015	16:12	13.97	Double Read
					VISIT 4	03NOV2015	15:46	14.625	Double Read
					VISIT 6	30MAR2016	16:15	13.745	Double Read
					VISIT 7	21SEP2016	15:59	13.135	Double Read
					VISIT 8	30AUG2017	16:17	14.45	Double Read
					VISIT 11	09SEP2020	16:04	11.83	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22JUN2015	16:11	14.32	Double Read
					VISIT 3A	21SEP2015	16:12	14.36	Double Read
					VISIT 4	03NOV2015	15:46	14.37	Double Read
					VISIT 6	30MAR2016	16:15	15.085	Double Read
					VISIT 7	21SEP2016	15:59	14.52	Double Read
					VISIT 8	30AUG2017	16:17	15.525	Double Read
					VISIT 11	09SEP2020	16:04	14.71	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22JUN2015	16:11	8.08383	Double Read
					VISIT 3A	21SEP2015	16:12	7.72323	Double Read
					VISIT 4	03NOV2015	15:46	7.13188	Double Read
					VISIT 6	30MAR2016	16:15	7.42726	Double Read
					VISIT 7	21SEP2016	15:59	7.962755	Double Read
					VISIT 8	30AUG2017	16:17	7.975875	Double Read
					VISIT 11	09SEP2020	16:04	6.489685	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22JUN2015	16:11	10.4425	Double Read
					VISIT 3A	21SEP2015	16:12	10.22804	Double Read
					VISIT 4	03NOV2015	15:46	10.4712	Double Read
					VISIT 6	30MAR2016	16:15	10.59705	Double Read
					VISIT 7	21SEP2016	15:59	11.0446	Double Read
					VISIT 8	30AUG2017	16:17	11.40255	Double Read
					VISIT 11	09SEP2020	16:04	11.0235	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	22JUN2015	16:11	N	Double Read
					VISIT 3A	21SEP2015	16:12	N	Double Read
					VISIT 4	03NOV2015	15:46	N	Double Read
					VISIT 6	30MAR2016	16:15	N	Double Read
					VISIT 7	21SEP2016	15:59	N	Double Read
					VISIT 8	30AUG2017	16:17	N	Double Read
					VISIT 11	09SEP2020	16:04	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22JUN2015	16:11	N	Double Read
					VISIT 3A	21SEP2015	16:12	N	Double Read
					VISIT 4	03NOV2015	15:46	N	Double Read
					VISIT 6	30MAR2016	16:15	N	Double Read
					VISIT 7	21SEP2016	15:59	N	Double Read
					VISIT 8	30AUG2017	16:17	N	Double Read
					VISIT 11	09SEP2020	16:04	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	22JUN2015	16:11	N	Double Read
					VISIT 3A	21SEP2015	16:12	N	Double Read
					VISIT 4	03NOV2015	15:46	N	Double Read
					VISIT 6	30MAR2016	16:15	N	Double Read
					VISIT 7	21SEP2016	15:59	N	Double Read
					VISIT 8	30AUG2017	16:17	N	Double Read
					VISIT 11	09SEP2020	16:04	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22JUN2015	16:11	N	Double Read
					VISIT 3A	21SEP2015	16:12	N	Double Read
					VISIT 4	03NOV2015	15:46	N	Double Read
					VISIT 6	30MAR2016	16:15	N	Double Read
					VISIT 7	21SEP2016	15:59	N	Double Read
					VISIT 8	30AUG2017	16:17	N	Double Read
					VISIT 11	09SEP2020	16:04	N	Double Read
Normal lordotic LS	5_S		General		Baseline	22JUN2015	16:11	Y	Double Read
					VISIT 3A	21SEP2015	16:12	Y	Double Read
					VISIT 4	03NOV2015	15:46	Y	Double Read
					VISIT 6	30MAR2016	16:15	Y	Double Read
					VISIT 7	21SEP2016	15:59	Y	Double Read
					VISIT 8	30AUG2017	16:17	Y	Double Read
					VISIT 11	09SEP2020	16:04	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	22JUN2015	16:11	0	Double Read
					VISIT 3A	21SEP2015	16:12	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	03NOV2015	15:46	0	Double Read
					VISIT 6	30MAR2016	16:15	0	Double Read
					VISIT 7	21SEP2016	15:59	0	Double Read
					VISIT 8	30AUG2017	16:17	0	Double Read
					VISIT 11	09SEP2020	16:04	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22JUN2015	16:11	0	Double Read
					VISIT 3A	21SEP2015	16:12	0	Double Read
					VISIT 4	03NOV2015	15:46	0	Double Read
					VISIT 6	30MAR2016	16:15	0	Double Read
					VISIT 7	21SEP2016	15:59	0	Double Read
					VISIT 8	30AUG2017	16:17	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 11	09SEP2020	16:04	0	Double Read
					Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04	N	Double Read
					Baseline	22JUN2015	16:11	N	Double Read
					VISIT 3A	21SEP2015	16:12	N	Double Read
					VISIT 4	03NOV2015	15:46	N	Double Read
					VISIT 6	30MAR2016	16:15	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	21SEP2016	15:59	N	Double Read
					VISIT 8	30AUG2017	16:17	N	Double Read
					VISIT 11	09SEP2020	16:04	N	Double Read
					VISIT 3A	21SEP2015	16:12	N	Double Read
					VISIT 4	03NOV2015	15:46	N	Double Read
					VISIT 6	30MAR2016	16:15	N	Double Read
					VISIT 7	21SEP2016	15:59	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	30AUG2017	16:17	N	Double Read
					VISIT 11	09SEP2020	16:04	N	Double Read
Relevant scoliosis	5_S		General		Baseline	22JUN2015	16:11	N	Double Read
					VISIT 3A	21SEP2015	16:12	N	Double Read
					VISIT 4	03NOV2015	15:46	N	Double Read
					VISIT 6	30MAR2016	16:15	N	Double Read
					VISIT 7	21SEP2016	15:59	N	Double Read
					VISIT 8	30AUG2017	16:17	N	Double Read
					VISIT 11	09SEP2020	16:04	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	22JUN2015	16:11	N	Double Read
					VISIT 3A	21SEP2015	16:12	N	Double Read
					VISIT 4	03NOV2015	15:46	N	Double Read
					VISIT 6	30MAR2016	16:15	N	Double Read
					VISIT 7	21SEP2016	15:59	N	Double Read
					VISIT 8	30AUG2017	16:17	N	Double Read
					VISIT 11	09SEP2020	16:04	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22JUN2015	16:11	N	Double Read
					VISIT 3A	21SEP2015	16:12	N	Double Read
					VISIT 4	03NOV2015	15:46	N	Double Read
					VISIT 6	30MAR2016	16:15	N	Double Read
					VISIT 7	21SEP2016	15:59	N	Double Read
					VISIT 8	30AUG2017	16:17	N	Double Read
					VISIT 11	09SEP2020	16:04	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22JUN2015	16:11	65.5672	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	21SEP2015	16:12	65.62688	Double Read
					VISIT 4	03NOV2015	15:46	81.80912	Double Read
					VISIT 6	30MAR2016	16:15	64.62784	Double Read
					VISIT 7	21SEP2016	15:59	72.13008	Double Read
					VISIT 8	30AUG2017	16:17	80.0216	Double Read
					VISIT 11	09SEP2020	16:04	71.34672	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22JUN2015	16:11	105.77536	Double Read
					VISIT 3A	21SEP2015	16:12	104.16	Double Read
					VISIT 4	03NOV2015	15:46	108.30384	Double Read
					VISIT 6	30MAR2016	16:15	104.76784	Double Read
					VISIT 7	21SEP2016	15:59	103.78656	Double Read
					VISIT 8	30AUG2017	16:17	102.69088	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	09SEP2020	16:04	100.0528	Double Read
					VISIT 3A	21SEP2015	16:12		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	09SEP2020	16:04		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	22JUN2015	16:11	lower	Double Read
					VISIT 3A	21SEP2015	16:12	lower	Double Read
					VISIT 4	03NOV2015	15:46	lower	Double Read
					VISIT 6	30MAR2016	16:15	lower	Double Read
					VISIT 7	21SEP2016	15:59	lower	Double Read
					VISIT 8	30AUG2017	16:17	lower	Double Read
					VISIT 11	09SEP2020	16:04	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22JUN2015	16:11	6.6148938338	Double Read
					VISIT 3A	21SEP2015	16:12	7.1796636657	Double Read
					VISIT 4	03NOV2015	15:46	4.9849091217	Double Read
					VISIT 6	30MAR2016	16:15	7.9064786818	Double Read
					VISIT 7	21SEP2016	15:59	8.0670834041	Double Read
					VISIT 8	30AUG2017	16:17	9.7484083574	Double Read
					VISIT 11	09SEP2020	16:04	3.7357023951	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22JUN2015	16:11	4.0343128928	Double Read
					VISIT 3A	21SEP2015	16:12	6.3416544929	Double Read
					VISIT 4	03NOV2015	15:46	5.2221572957	Double Read
					VISIT 6	30MAR2016	16:15	2.5237166638	Double Read
					VISIT 7	21SEP2016	15:59	4.0767793443	Double Read
					VISIT 8	30AUG2017	16:17	5.5206386954	Double Read
					VISIT 11	09SEP2020	16:04	6.0821403091	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22JUN2015	16:11	12795.0	Double Read
					VISIT 3A	21SEP2015	16:12	13279.0	Double Read
					VISIT 4	03NOV2015	15:46	13274.5	Double Read
					VISIT 6	30MAR2016	16:15	12439.0	Double Read
					VISIT 7	21SEP2016	15:59	12530.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	30AUG2017	16:17	13553.5	Double Read
					VISIT 11	09SEP2020	16:04	8227.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read
					VISIT 11	09SEP2020	16:04		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22JUN2015	16:11	16469.0	Double Read
					VISIT 3A	21SEP2015	16:12	16856.5	Double Read
					VISIT 4	03NOV2015	15:46	16050.5	Double Read
					VISIT 6	30MAR2016	16:15	16473.5	Double Read
					VISIT 7	21SEP2016	15:59	17246.0	Double Read
					VISIT 8	30AUG2017	16:17	16888.5	Double Read
					VISIT 11	09SEP2020	16:04	13011.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	22JUN2015	16:11		Double Read
					VISIT 3A	21SEP2015	16:12		Double Read
					VISIT 4	03NOV2015	15:46		Double Read
					VISIT 6	30MAR2016	16:15		Double Read
					VISIT 7	21SEP2016	15:59		Double Read
					VISIT 8	30AUG2017	16:17		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0144 Age=36 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	09SEP2020	16:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	14JUL2015	17:01	3	Double Read
					VISIT 3A	05OCT2015	15:45	3	Double Read
					VISIT 4	19NOV2015	16:10	3	Double Read
					VISIT 6	05APR2016	16:22	3	Double Read
					VISIT 7	04OCT2016	16:07	4	Double Read
					VISIT 8	20SEP2017	16:11	3	Double Read
					VISIT 11	30SEP2020	16:08	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	17:01	2	Double Read
					VISIT 3A	05OCT2015	15:45	2	Double Read
					VISIT 4	19NOV2015	16:10	2	Double Read
					VISIT 6	05APR2016	16:22	2	Double Read
					VISIT 7	04OCT2016	16:07	2	Double Read
					VISIT 8	20SEP2017	16:11	2	Double Read
					VISIT 11	30SEP2020	16:08	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	14JUL2015	17:01	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	05OCT2015	15:45	N	Double Read
					VISIT 4	19NOV2015	16:10	N	Double Read
					VISIT 6	05APR2016	16:22	N	Double Read
					VISIT 7	04OCT2016	16:07	N	Double Read
					VISIT 8	20SEP2017	16:11	N	Double Read
					VISIT 11	30SEP2020	16:08	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	17:01	N	Double Read
					VISIT 3A	05OCT2015	15:45	N	Double Read
					VISIT 4	19NOV2015	16:10	N	Double Read
					VISIT 6	05APR2016	16:22	N	Double Read
					VISIT 7	04OCT2016	16:07	N	Double Read
					VISIT 8	20SEP2017	16:11	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	30SEP2020	16:08	N	Double Read
					Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
					Baseline	14JUL2015	17:01	Y	Double Read
					VISIT 3A	05OCT2015	15:45	N	Double Read
					VISIT 4	19NOV2015	16:10	Y	Double Read
					VISIT 6	05APR2016	16:22	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	04OCT2016	16:07	N	Double Read
					VISIT 8	20SEP2017	16:11	N	Double Read
					VISIT 11	30SEP2020	16:08	Y	Double Read
					Baseline	14JUL2015	17:01	N	Double Read
					VISIT 3A	05OCT2015	15:45	N	Double Read
					VISIT 4	19NOV2015	16:10	N	Double Read
					VISIT 6	05APR2016	16:22	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	04OCT2016	16:07	N	Double Read
					VISIT 8	20SEP2017	16:11	N	Double Read
					VISIT 11	30SEP2020	16:08	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	14JUL2015	17:01	N	Double Read
					VISIT 3A	05OCT2015	15:45	N	Double Read
					VISIT 4	19NOV2015	16:10	N	Double Read
					VISIT 6	05APR2016	16:22	N	Double Read
					VISIT 7	04OCT2016	16:07	N	Double Read
					VISIT 8	20SEP2017	16:11	N	Double Read
					VISIT 11	30SEP2020	16:08	N	Double Read
Fracture	5_S		General		Baseline	14JUL2015	17:01	N	Double Read
					VISIT 3A	05OCT2015	15:45	N	Double Read
					VISIT 4	19NOV2015	16:10	N	Double Read
					VISIT 6	05APR2016	16:22	N	Double Read
					VISIT 7	04OCT2016	16:07	N	Double Read
					VISIT 8	20SEP2017	16:11	N	Double Read
					VISIT 11	30SEP2020	16:08	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JUL2015	17:01	11.525	Double Read
					VISIT 3A	05OCT2015	15:45	13.76	Double Read
					VISIT 4	19NOV2015	16:10	14.195	Double Read
					VISIT 6	05APR2016	16:22	13.775	Double Read
					VISIT 7	04OCT2016	16:07	13.495	Double Read
					VISIT 8	20SEP2017	16:11	13.515	Double Read
					VISIT 11	30SEP2020	16:08	13.38	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	17:01	14.055	Double Read
					VISIT 3A	05OCT2015	15:45	14.465	Double Read
					VISIT 4	19NOV2015	16:10	15.48	Double Read
					VISIT 6	05APR2016	16:22	15.0	Double Read
					VISIT 7	04OCT2016	16:07	13.95	Double Read
					VISIT 8	20SEP2017	16:11	14.38	Double Read
					VISIT 11	30SEP2020	16:08	15.875	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JUL2015	17:01	9.738165	Double Read
					VISIT 3A	05OCT2015	15:45	10.38005	Double Read
					VISIT 4	19NOV2015	16:10	10.40425	Double Read
					VISIT 6	05APR2016	16:22	9.787495	Double Read
					VISIT 7	04OCT2016	16:07	9.99084	Double Read
					VISIT 8	20SEP2017	16:11	9.896145	Double Read
					VISIT 11	30SEP2020	16:08	9.981795	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	17:01	11.5141	Double Read
					VISIT 3A	05OCT2015	15:45	12.2843	Double Read
					VISIT 4	19NOV2015	16:10	12.0638	Double Read
					VISIT 6	05APR2016	16:22	11.9367	Double Read
					VISIT 7	04OCT2016	16:07	11.6195	Double Read
					VISIT 8	20SEP2017	16:11	12.08305	Double Read
					VISIT 11	30SEP2020	16:08	12.2546	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	14JUL2015	17:01	N	Double Read
					VISIT 3A	05OCT2015	15:45	N	Double Read
					VISIT 4	19NOV2015	16:10	N	Double Read
					VISIT 6	05APR2016	16:22	N	Double Read
					VISIT 7	04OCT2016	16:07	N	Double Read
					VISIT 8	20SEP2017	16:11	N	Double Read
					VISIT 11	30SEP2020	16:08	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	17:01	N	Double Read
					VISIT 3A	05OCT2015	15:45	N	Double Read
					VISIT 4	19NOV2015	16:10	N	Double Read
					VISIT 6	05APR2016	16:22	N	Double Read
					VISIT 7	04OCT2016	16:07	N	Double Read
					VISIT 8	20SEP2017	16:11	N	Double Read
					VISIT 11	30SEP2020	16:08	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	14JUL2015	17:01	N	Double Read
					VISIT 3A	05OCT2015	15:45	N	Double Read
					VISIT 4	19NOV2015	16:10	N	Double Read
					VISIT 6	05APR2016	16:22	N	Double Read
					VISIT 7	04OCT2016	16:07	N	Double Read
					VISIT 8	20SEP2017	16:11	N	Double Read
					VISIT 11	30SEP2020	16:08	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	17:01	N	Double Read
					VISIT 3A	05OCT2015	15:45	N	Double Read
					VISIT 4	19NOV2015	16:10	N	Double Read
					VISIT 6	05APR2016	16:22	N	Double Read
					VISIT 7	04OCT2016	16:07	N	Double Read
					VISIT 8	20SEP2017	16:11	N	Double Read
					VISIT 11	30SEP2020	16:08	N	Double Read
Normal lordotic LS	5_S		General		Baseline	14JUL2015	17:01	Y	Double Read
					VISIT 3A	05OCT2015	15:45	Y	Double Read
					VISIT 4	19NOV2015	16:10	Y	Double Read
					VISIT 6	05APR2016	16:22	Y	Double Read
					VISIT 7	04OCT2016	16:07	Y	Double Read
					VISIT 8	20SEP2017	16:11	Y	Double Read
					VISIT 11	30SEP2020	16:08	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	14JUL2015	17:01	0	Double Read
					VISIT 3A	05OCT2015	15:45	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	19NOV2015	16:10	0	Double Read
					VISIT 6	05APR2016	16:22	0	Double Read
					VISIT 7	04OCT2016	16:07	1	Double Read
					VISIT 8	20SEP2017	16:11	1	Double Read
					VISIT 11	30SEP2020	16:08	1	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	17:01	0	Double Read
					VISIT 3A	05OCT2015	15:45	0	Double Read
					VISIT 4	19NOV2015	16:10	0	Double Read
					VISIT 6	05APR2016	16:22	0	Double Read
					VISIT 7	04OCT2016	16:07	0	Double Read
					VISIT 8	20SEP2017	16:11	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 11	30SEP2020	16:08	0	Double Read
					Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
					Baseline	14JUL2015	17:01	N	Double Read
					VISIT 3A	05OCT2015	15:45	N	Double Read
					VISIT 4	19NOV2015	16:10	N	Double Read
					VISIT 6	05APR2016	16:22	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	04OCT2016	16:07	N	Double Read
					VISIT 8	20SEP2017	16:11	N	Double Read
					VISIT 11	30SEP2020	16:08	N	Double Read
					VISIT 3A	05OCT2015	15:45	N	Double Read
					VISIT 4	19NOV2015	16:10	N	Double Read
					VISIT 6	05APR2016	16:22	N	Double Read
					VISIT 7	04OCT2016	16:07	N	Double Read
					VISIT 7	04OCT2016	16:07	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	20SEP2017	16:11	N	Double Read
					VISIT 11	30SEP2020	16:08	N	Double Read
Relevant scoliosis	5_S		General		Baseline	14JUL2015	17:01	N	Double Read
					VISIT 3A	05OCT2015	15:45	N	Double Read
					VISIT 4	19NOV2015	16:10	N	Double Read
					VISIT 6	05APR2016	16:22	N	Double Read
					VISIT 7	04OCT2016	16:07	N	Double Read
					VISIT 8	20SEP2017	16:11	N	Double Read
					VISIT 11	30SEP2020	16:08	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	14JUL2015	17:01	N	Double Read
					VISIT 3A	05OCT2015	15:45	N	Double Read
					VISIT 4	19NOV2015	16:10	N	Double Read
					VISIT 6	05APR2016	16:22	N	Double Read
					VISIT 7	04OCT2016	16:07	N	Double Read
					VISIT 8	20SEP2017	16:11	N	Double Read
					VISIT 11	30SEP2020	16:08	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	17:01	N	Double Read
					VISIT 3A	05OCT2015	15:45	N	Double Read
					VISIT 4	19NOV2015	16:10	N	Double Read
					VISIT 6	05APR2016	16:22	N	Double Read
					VISIT 7	04OCT2016	16:07	N	Double Read
					VISIT 8	20SEP2017	16:11	N	Double Read
					VISIT 11	30SEP2020	16:08	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JUL2015	17:01	71.92048	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	05OCT2015	15:45	73.30272	Double Read
					VISIT 4	19NOV2015	16:10	73.172	Double Read
					VISIT 6	05APR2016	16:22	70.66528	Double Read
					VISIT 7	04OCT2016	16:07	65.36	Double Read
					VISIT 8	20SEP2017	16:11	66.39328	Double Read
					VISIT 11	30SEP2020	16:08	69.89792	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	17:01	108.21136	Double Read
					VISIT 3A	05OCT2015	15:45	106.53504	Double Read
					VISIT 4	19NOV2015	16:10	106.73648	Double Read
					VISIT 6	05APR2016	16:22	107.80928	Double Read
					VISIT 7	04OCT2016	16:07	110.03152	Double Read
					VISIT 8	20SEP2017	16:11	109.74592	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	30SEP2020	16:08	107.88608	Double Read
					VISIT 3A	05OCT2015	15:45		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	30SEP2020	16:08		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	14JUL2015	17:01	lower	Double Read
					VISIT 3A	05OCT2015	15:45	lower	Double Read
					VISIT 4	19NOV2015	16:10	lower	Double Read
					VISIT 6	05APR2016	16:22	lower	Double Read
					VISIT 7	04OCT2016	16:07	lower	Double Read
					VISIT 8	20SEP2017	16:11	lower	Double Read
					VISIT 11	30SEP2020	16:08	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JUL2015	17:01	7.6354679803	Double Read
					VISIT 3A	05OCT2015	15:45	6.2952811279	Double Read
					VISIT 4	19NOV2015	16:10	9.4639510786	Double Read
					VISIT 6	05APR2016	16:22	7.9820757601	Double Read
					VISIT 7	04OCT2016	16:07	8.7619976218	Double Read
					VISIT 8	20SEP2017	16:11	9.3167385765	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	VISIT 11	30SEP2020	16:08	14.103577373	Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	VISIT 11	30SEP2020	16:08		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	17:01	7.4325734669	Double Read
					VISIT 3A	05OCT2015	15:45	2.5237166638	Double Read
					VISIT 4	19NOV2015	16:10	2.8452522507	Double Read
					VISIT 6	05APR2016	16:22	5.9453032104	Double Read
					VISIT 7	04OCT2016	16:07	9.3426193307	Double Read
					VISIT 8	20SEP2017	16:11	2.5156310514	Double Read
					VISIT 11	30SEP2020	16:08	4.1447256667	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JUL2015	17:01	10352.0	Double Read
					VISIT 3A	05OCT2015	15:45	12094.5	Double Read
					VISIT 4	19NOV2015	16:10	11406.5	Double Read
					VISIT 6	05APR2016	16:22	12041.5	Double Read
					VISIT 7	04OCT2016	16:07	11674.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	20SEP2017	16:11	11140.0	Double Read
					VISIT 11	30SEP2020	16:08	10651.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read
					VISIT 11	30SEP2020	16:08		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	17:01	14256.0	Double Read
					VISIT 3A	05OCT2015	15:45	15631.0	Double Read
					VISIT 4	19NOV2015	16:10	15986.0	Double Read
					VISIT 6	05APR2016	16:22	16075.5	Double Read
					VISIT 7	04OCT2016	16:07	15212.5	Double Read
					VISIT 8	20SEP2017	16:11	15777.5	Double Read
					VISIT 11	30SEP2020	16:08	15759.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	14JUL2015	17:01		Double Read
					VISIT 3A	05OCT2015	15:45		Double Read
					VISIT 4	19NOV2015	16:10		Double Read
					VISIT 6	05APR2016	16:22		Double Read
					VISIT 7	04OCT2016	16:07		Double Read
					VISIT 8	20SEP2017	16:11		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0145 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	30SEP2020	16:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0146 Age=50 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	15JUL2015	17:05	3	Double Read
					VISIT 4	27AUG2015	16:16	3	Double Read
					VISIT 6	20JAN2016	17:05	4	Double Read
					VISIT 7	06JUL2016	16:20	3	Double Read
					VISIT 8	21JUN2017	16:30	4	Double Read
					VISIT 11	26AUG2020	16:14	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15JUL2015	17:05	3	Double Read
					VISIT 4	27AUG2015	16:16	3	Double Read
					VISIT 6	20JAN2016	17:05	3	Double Read
					VISIT 7	06JUL2016	16:20	3	Double Read
					VISIT 8	21JUN2017	16:30	4	Double Read
					VISIT 11	26AUG2020	16:14	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	15JUL2015	17:05	N	Double Read
					VISIT 4	27AUG2015	16:16	N	Double Read
					VISIT 6	20JAN2016	17:05	N	Double Read
					VISIT 7	06JUL2016	16:20	N	Double Read
					VISIT 8	21JUN2017	16:30	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0146 Age=50 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 11	26AUG2020	16:14	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15JUL2015	17:05	N	Double Read
					VISIT 4	27AUG2015	16:16	N	Double Read
					VISIT 6	20JAN2016	17:05	N	Double Read
					VISIT 7	06JUL2016	16:20	N	Double Read
					VISIT 8	21JUN2017	16:30	N	Double Read
					VISIT 11	26AUG2020	16:14	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	15JUL2015	17:05	Y	Double Read
					VISIT 4	27AUG2015	16:16	Y	Double Read
					VISIT 6	20JAN2016	17:05	Y	Double Read
					VISIT 7	06JUL2016	16:20	Y	Double Read
					VISIT 8	21JUN2017	16:30	Y	Double Read
					VISIT 11	26AUG2020	16:14	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15JUL2015	17:05	N	Double Read
					VISIT 4	27AUG2015	16:16	N	Double Read
					VISIT 6	20JAN2016	17:05	N	Double Read
					VISIT 7	06JUL2016	16:20	N	Double Read
					VISIT 8	21JUN2017	16:30	N	Double Read
					VISIT 11	26AUG2020	16:14	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	15JUL2015	17:05	N	Double Read
					VISIT 4	27AUG2015	16:16	N	Double Read
					VISIT 6	20JAN2016	17:05	N	Double Read
					VISIT 7	06JUL2016	16:20	N	Double Read
					VISIT 8	21JUN2017	16:30	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0146 Age=50 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 11	26AUG2020	16:14	N	Double Read
Fracture	5_S		General		Baseline	15JUL2015	17:05	N	Double Read
					VISIT 4	27AUG2015	16:16	N	Double Read
					VISIT 6	20JAN2016	17:05	N	Double Read
					VISIT 7	06JUL2016	16:20	N	Double Read
					VISIT 8	21JUN2017	16:30	N	Double Read
					VISIT 11	26AUG2020	16:14	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15JUL2015	17:05	18.19	Double Read
					VISIT 4	27AUG2015	16:16	17.085	Double Read
					VISIT 6	20JAN2016	17:05	17.725	Double Read
					VISIT 7	06JUL2016	16:20	17.93	Double Read
					VISIT 8	21JUN2017	16:30	19.415	Double Read
					VISIT 11	26AUG2020	16:14	15.06	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15JUL2015	17:05	17.945	Double Read
					VISIT 4	27AUG2015	16:16	16.54	Double Read
					VISIT 6	20JAN2016	17:05	17.93	Double Read
					VISIT 7	06JUL2016	16:20	18.05	Double Read
					VISIT 8	21JUN2017	16:30	19.35	Double Read
					VISIT 11	26AUG2020	16:14	16.245	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0146 Age=50 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15JUL2015	17:05	7.654245	Double Read
					VISIT 4	27AUG2015	16:16	7.577085	Double Read
					VISIT 6	20JAN2016	17:05	7.49369	Double Read
					VISIT 7	06JUL2016	16:20	7.51016	Double Read
					VISIT 8	21JUN2017	16:30	7.52163	Double Read
					VISIT 11	26AUG2020	16:14	6.636015	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15JUL2015	17:05	11.0498	Double Read
					VISIT 4	27AUG2015	16:16	10.95915	Double Read
					VISIT 6	20JAN2016	17:05	10.93905	Double Read
					VISIT 7	06JUL2016	16:20	10.4947	Double Read
					VISIT 8	21JUN2017	16:30	10.96585	Double Read
					VISIT 11	26AUG2020	16:14	11.05075	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	15JUL2015	17:05	N	Double Read
					VISIT 4	27AUG2015	16:16	N	Double Read
					VISIT 6	20JAN2016	17:05	N	Double Read
					VISIT 7	06JUL2016	16:20	N	Double Read
					VISIT 8	21JUN2017	16:30	N	Double Read
					VISIT 11	26AUG2020	16:14	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0146 Age=50 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15JUL2015	17:05	N	Double Read
					VISIT 4	27AUG2015	16:16	N	Double Read
					VISIT 6	20JAN2016	17:05	N	Double Read
					VISIT 7	06JUL2016	16:20	N	Double Read
					VISIT 8	21JUN2017	16:30	N	Double Read
					VISIT 11	26AUG2020	16:14	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	15JUL2015	17:05	N	Double Read
					VISIT 4	27AUG2015	16:16	N	Double Read
					VISIT 6	20JAN2016	17:05	N	Double Read
					VISIT 7	06JUL2016	16:20	N	Double Read
					VISIT 8	21JUN2017	16:30	N	Double Read
					VISIT 11	26AUG2020	16:14	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15JUL2015	17:05	N	Double Read
					VISIT 4	27AUG2015	16:16	N	Double Read
					VISIT 6	20JAN2016	17:05	N	Double Read
					VISIT 7	06JUL2016	16:20	N	Double Read
					VISIT 8	21JUN2017	16:30	N	Double Read
					VISIT 11	26AUG2020	16:14	N	Double Read
Normal lordotic LS	5_S		General		Baseline	15JUL2015	17:05	Y	Double Read
					VISIT 4	27AUG2015	16:16	Y	Double Read
					VISIT 6	20JAN2016	17:05	Y	Double Read
					VISIT 7	06JUL2016	16:20	Y	Double Read
					VISIT 8	21JUN2017	16:30	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0146 Age=50 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	5_S		General		VISIT 11	26AUG2020	16:14	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	15JUL2015	17:05	2	Double Read
					VISIT 4	27AUG2015	16:16	0	Double Read
					VISIT 6	20JAN2016	17:05	1	Double Read
					VISIT 7	06JUL2016	16:20	2	Double Read
					VISIT 8	21JUN2017	16:30	2	Double Read
					VISIT 11	26AUG2020	16:14	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15JUL2015	17:05	0	Double Read
					VISIT 4	27AUG2015	16:16	0	Double Read
					VISIT 6	20JAN2016	17:05	0	Double Read
					VISIT 7	06JUL2016	16:20	0	Double Read
					VISIT 8	21JUN2017	16:30	0	Double Read
					VISIT 11	26AUG2020	16:14	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	15JUL2015	17:05	N	Double Read
					VISIT 4	27AUG2015	16:16	N	Double Read
					VISIT 6	20JAN2016	17:05	N	Double Read
					VISIT 7	06JUL2016	16:20	N	Double Read
					VISIT 8	21JUN2017	16:30	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0146 Age=50 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 11	26AUG2020	16:14	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15JUL2015	17:05	N	Double Read
					VISIT 4	27AUG2015	16:16	N	Double Read
					VISIT 6	20JAN2016	17:05	N	Double Read
					VISIT 7	06JUL2016	16:20	N	Double Read
					VISIT 8	21JUN2017	16:30	N	Double Read
					VISIT 11	26AUG2020	16:14	N	Double Read
Relevant scoliosis	5_S		General		Baseline	15JUL2015	17:05	N	Double Read
					VISIT 4	27AUG2015	16:16	N	Double Read
					VISIT 6	20JAN2016	17:05	N	Double Read
					VISIT 7	06JUL2016	16:20	N	Double Read
					VISIT 8	21JUN2017	16:30	N	Double Read
					VISIT 11	26AUG2020	16:14	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	15JUL2015	17:05	N	Double Read
					VISIT 4	27AUG2015	16:16	N	Double Read
					VISIT 6	20JAN2016	17:05	N	Double Read
					VISIT 7	06JUL2016	16:20	N	Double Read
					VISIT 8	21JUN2017	16:30	N	Double Read
					VISIT 11	26AUG2020	16:14	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15JUL2015	17:05	N	Double Read
					VISIT 4	27AUG2015	16:16	N	Double Read
					VISIT 6	20JAN2016	17:05	N	Double Read
					VISIT 7	06JUL2016	16:20	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0146 Age=50 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	21JUN2017	16:30	N	Double Read
					VISIT 11	26AUG2020	16:14	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15JUL2015	17:05	73.4	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0146 Age=50 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 4	27AUG2015	16:16	72.18272	Double Read
					VISIT 6	20JAN2016	17:05	73.76032	Double Read
					VISIT 7	06JUL2016	16:20	82.88416	Double Read
					VISIT 8	21JUN2017	16:30	75.42112	Double Read
					VISIT 11	26AUG2020	16:14	57.91776	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15JUL2015	17:05	69.54688	Double Read
					VISIT 4	27AUG2015	16:16	72.82224	Double Read
					VISIT 6	20JAN2016	17:05	74.9968	Double Read
					VISIT 7	06JUL2016	16:20	84.65696	Double Read
					VISIT 8	21JUN2017	16:30	78.9816	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	26AUG2020	16:14	63.39712	Double Read
					Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0146 Age=50 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0146 Age=50 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	15JUL2015	17:05	equal	Double Read
					VISIT 4	27AUG2015	16:16	equal	Double Read
					VISIT 6	20JAN2016	17:05	equal	Double Read
					VISIT 7	06JUL2016	16:20	equal	Double Read
					VISIT 8	21JUN2017	16:30	equal	Double Read
					VISIT 11	26AUG2020	16:14	equal	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0146 Age=50 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0146 Age=50 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15JUL2015	17:05	9.2633531510	Double Read
					VISIT 4	27AUG2015	16:16	9.6794836079	Double Read
					VISIT 6	20JAN2016	17:05	7.7321284185	Double Read
					VISIT 7	06JUL2016	16:20	13.079667063	Double Read
					VISIT 8	21JUN2017	16:30	13.357954815	Double Read
								7	

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0146 Age=50 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 11	26AUG2020	16:14	7.57034822491	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15JUL2015	17:05	8.80693731952	Double Read
					VISIT 4	27AUG2015	16:16	8.69551214541	Double Read
					VISIT 6	20JAN2016	17:05	12.3754917615	Double Read
					VISIT 7	06JUL2016	16:20	8.50505180907	Double Read
					VISIT 8	21JUN2017	16:30	9.57922201461	Double Read
					VISIT 11	26AUG2020	16:14	9.22330558858	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0146 Age=50 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	26AUG2020	16:14		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15JUL2015	17:05	13909.0	Double Read
					VISIT 4	27AUG2015	16:16	14301.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0146 Age=50 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 6	20JAN2016	17:05	13844.0	Double Read
					VISIT 7	06JUL2016	16:20	14107.5	Double Read
					VISIT 8	21JUN2017	16:30	14490.5	Double Read
					VISIT 11	26AUG2020	16:14	12091.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15JUL2015	17:05	20505.5	Double Read
					VISIT 4	27AUG2015	16:16	20273.0	Double Read
					VISIT 6	20JAN2016	17:05	20132.0	Double Read
					VISIT 7	06JUL2016	16:20	21047.5	Double Read
					VISIT 8	21JUN2017	16:30	21894.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	15JUL2015	17:05		Double Read
					VISIT 4	27AUG2015	16:16		Double Read
					VISIT 6	20JAN2016	17:05		Double Read
					VISIT 7	06JUL2016	16:20		Double Read
					VISIT 8	21JUN2017	16:30		Double Read
					VISIT 11	26AUG2020	16:14	20674.0	Double Read
					VISIT 11	26AUG2020	16:14		Double Read
					VISIT 11	26AUG2020	16:14		Double Read
					VISIT 11	26AUG2020	16:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	19AUG2015	16:32	2	Double Read
					VISIT 3A	17NOV2015	16:22	2	Double Read
					VISIT 4	05JAN2016	15:49	2	Double Read
					VISIT 6	11MAY2016	16:27	2	Double Read
					VISIT 7	16NOV2016	16:29	2	Double Read
					VISIT 8	15NOV2017	16:31	2	Double Read
					VISIT 11	04NOV2020	16:19	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	19AUG2015	16:32	4	Double Read
					VISIT 3A	17NOV2015	16:22	3	Double Read
					VISIT 4	05JAN2016	15:49	3	Double Read
					VISIT 6	11MAY2016	16:27	3	Double Read
					VISIT 7	16NOV2016	16:29	4	Double Read
					VISIT 8	15NOV2017	16:31	4	Double Read
					VISIT 11	04NOV2020	16:19	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	19AUG2015	16:32	3	Double Read
					VISIT 3A	17NOV2015	16:22	3	Double Read
					VISIT 4	05JAN2016	15:49	3	Double Read
					VISIT 6	11MAY2016	16:27	3	Double Read
					VISIT 7	16NOV2016	16:29	3	Double Read
					VISIT 8	15NOV2017	16:31	3	Double Read
					VISIT 11	04NOV2020	16:19	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	19AUG2015	16:32	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
					VISIT 7	16NOV2016	16:29	N	Double Read
					VISIT 8	15NOV2017	16:31	N	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	19AUG2015	16:32	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
					VISIT 7	16NOV2016	16:29	N	Double Read
					VISIT 8	15NOV2017	16:31	N	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	19AUG2015	16:32	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
					VISIT 7	16NOV2016	16:29	N	Double Read
					VISIT 8	15NOV2017	16:31	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 11	04NOV2020	16:19	N	Double Read
					Baseline	19AUG2015	16:32	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
					VISIT 7	16NOV2016	16:29	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		VISIT 8	15NOV2017	16:31	N	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read
					Baseline	19AUG2015	16:32	Y	Double Read
					VISIT 3A	17NOV2015	16:22	Y	Double Read
					VISIT 4	05JAN2016	15:49	Y	Double Read
					VISIT 6	11MAY2016	16:27	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	16NOV2016	16:29	Y	Double Read
					VISIT 8	15NOV2017	16:31	Y	Double Read
					VISIT 11	04NOV2020	16:19	Y	Double Read
					Baseline	19AUG2015	16:32	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	16NOV2016	16:29	N	Double Read
					VISIT 8	15NOV2017	16:31	Y	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	19AUG2015	16:32	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
					VISIT 7	16NOV2016	16:29	N	Double Read
					VISIT 8	15NOV2017	16:31	N	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read
Fracture	4_5		General		Baseline	19AUG2015	16:32	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
					VISIT 7	16NOV2016	16:29	N	Double Read
					VISIT 8	15NOV2017	16:31	N	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	19AUG2015	16:32	14.31	Double Read
					VISIT 3A	17NOV2015	16:22	13.895	Double Read
					VISIT 4	05JAN2016	15:49	14.02	Double Read
					VISIT 6	11MAY2016	16:27	14.975	Double Read
					VISIT 7	16NOV2016	16:29	14.105	Double Read
					VISIT 8	15NOV2017	16:31	12.865	Double Read
					VISIT 11	04NOV2020	16:19	13.625	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	19AUG2015	16:32	12.98	Double Read
					VISIT 3A	17NOV2015	16:22	11.93	Double Read
					VISIT 4	05JAN2016	15:49	12.78	Double Read
					VISIT 6	11MAY2016	16:27	12.795	Double Read
					VISIT 7	16NOV2016	16:29	10.88	Double Read
					VISIT 8	15NOV2017	16:31	9.19	Double Read
					VISIT 11	04NOV2020	16:19	10.355	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	19AUG2015	16:32	12.92	Double Read
					VISIT 3A	17NOV2015	16:22	11.385	Double Read
					VISIT 4	05JAN2016	15:49	12.31	Double Read
					VISIT 6	11MAY2016	16:27	14.14	Double Read
					VISIT 7	16NOV2016	16:29	11.13	Double Read
					VISIT 8	15NOV2017	16:31	10.715	Double Read
					VISIT 11	04NOV2020	16:19	12.58	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	19AUG2015	16:32	9.507455	Double Read
					VISIT 3A	17NOV2015	16:22	9.546975	Double Read
					VISIT 4	05JAN2016	15:49	9.128225	Double Read
					VISIT 6	11MAY2016	16:27	9.677465	Double Read
					VISIT 7	16NOV2016	16:29	8.989575	Double Read
					VISIT 8	15NOV2017	16:31	9.267495	Double Read
					VISIT 11	04NOV2020	16:19	9.325645	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	19AUG2015	16:32	7.700685	Double Read
					VISIT 3A	17NOV2015	16:22	7.972825	Double Read
					VISIT 4	05JAN2016	15:49	7.13689	Double Read
					VISIT 6	11MAY2016	16:27	7.21099	Double Read
					VISIT 7	16NOV2016	16:29	5.47659	Double Read
					VISIT 8	15NOV2017	16:31	6.191065	Double Read
					VISIT 11	04NOV2020	16:19	5.72811	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	19AUG2015	16:32	8.321625	Double Read
					VISIT 3A	17NOV2015	16:22	8.391355	Double Read
					VISIT 4	05JAN2016	15:49	7.61891	Double Read
					VISIT 6	11MAY2016	16:27	8.775465	Double Read
					VISIT 7	16NOV2016	16:29	8.72079	Double Read
					VISIT 8	15NOV2017	16:31	8.635545	Double Read
					VISIT 11	04NOV2020	16:19	8.728845	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	19AUG2015	16:32	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
					VISIT 7	16NOV2016	16:29	N	Double Read
					VISIT 8	15NOV2017	16:31	N	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	19AUG2015	16:32	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
					VISIT 7	16NOV2016	16:29	Y	Double Read
					VISIT 8	15NOV2017	16:31	N	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	19AUG2015	16:32	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
					VISIT 7	16NOV2016	16:29	N	Double Read
					VISIT 8	15NOV2017	16:31	N	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	19AUG2015	16:32	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
					VISIT 7	16NOV2016	16:29	N	Double Read
					VISIT 8	15NOV2017	16:31	N	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	19AUG2015	16:32	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
					VISIT 7	16NOV2016	16:29	N	Double Read
					VISIT 8	15NOV2017	16:31	N	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	19AUG2015	16:32	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
					VISIT 7	16NOV2016	16:29	N	Double Read
					VISIT 8	15NOV2017	16:31	N	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read
Normal lordotic LS	4_5		General		Baseline	19AUG2015	16:32	Y	Double Read
					VISIT 3A	17NOV2015	16:22	Y	Double Read
					VISIT 4	05JAN2016	15:49	Y	Double Read
					VISIT 6	11MAY2016	16:27	Y	Double Read
					VISIT 7	16NOV2016	16:29	Y	Double Read
					VISIT 8	15NOV2017	16:31	Y	Double Read
					VISIT 11	04NOV2020	16:19	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	19AUG2015	16:32	0	Double Read
					VISIT 3A	17NOV2015	16:22	0	Double Read
					VISIT 4	05JAN2016	15:49	0	Double Read
					VISIT 6	11MAY2016	16:27	0	Double Read
					VISIT 7	16NOV2016	16:29	0	Double Read
					VISIT 8	15NOV2017	16:31	0	Double Read
					VISIT 11	04NOV2020	16:19	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	19AUG2015	16:32	0	Double Read
					VISIT 3A	17NOV2015	16:22	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 4	05JAN2016	15:49	1	Double Read
					VISIT 6	11MAY2016	16:27	1	Double Read
					VISIT 7	16NOV2016	16:29	1	Double Read
					VISIT 8	15NOV2017	16:31	1	Double Read
					VISIT 11	04NOV2020	16:19	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	19AUG2015	16:32	0	Double Read
					VISIT 3A	17NOV2015	16:22	0	Double Read
					VISIT 4	05JAN2016	15:49	0	Double Read
					VISIT 6	11MAY2016	16:27	0	Double Read
					VISIT 7	16NOV2016	16:29	0	Double Read
					VISIT 8	15NOV2017	16:31	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 11	04NOV2020	16:19	0	Double Read
					Baseline	19AUG2015	16:32	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
					VISIT 7	16NOV2016	16:29	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	15NOV2017	16:31	N	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read
					Baseline	19AUG2015	16:32	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	16NOV2016	16:29	N	Double Read
					VISIT 8	15NOV2017	16:31	N	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
					VISIT 7	16NOV2016	16:29	N	Double Read
					VISIT 8	15NOV2017	16:31	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	15NOV2017	16:31	N	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read
Relevant scoliosis	4_5		General		Baseline	19AUG2015	16:32	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
					VISIT 7	16NOV2016	16:29	N	Double Read
					VISIT 8	15NOV2017	16:31	N	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	19AUG2015	16:32	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
					VISIT 7	16NOV2016	16:29	N	Double Read
					VISIT 8	15NOV2017	16:31	N	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	19AUG2015	16:32	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
					VISIT 7	16NOV2016	16:29	N	Double Read
					VISIT 8	15NOV2017	16:31	N	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	19AUG2015	16:32	N	Double Read
					VISIT 3A	17NOV2015	16:22	N	Double Read
					VISIT 4	05JAN2016	15:49	N	Double Read
					VISIT 6	11MAY2016	16:27	N	Double Read
					VISIT 7	16NOV2016	16:29	N	Double Read
					VISIT 8	15NOV2017	16:31	N	Double Read
					VISIT 11	04NOV2020	16:19	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22	100.10128	Double Read
					VISIT 4	05JAN2016	15:49	93.8736	Double Read
					VISIT 6	11MAY2016	16:27	94.19504	Double Read
					VISIT 7	16NOV2016	16:29	89.88464	Double Read
					VISIT 8	15NOV2017	16:31	91.75136	Double Read
					VISIT 11	04NOV2020	16:19	83.35456	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	19AUG2015	16:32		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	17NOV2015	16:22	76.8448	Double Read
					VISIT 4	05JAN2016	15:49	76.11792	Double Read
					VISIT 6	11MAY2016	16:27	78.084	Double Read
					VISIT 7	16NOV2016	16:29	76.33408	Double Read
					VISIT 8	15NOV2017	16:31	68.9336	Double Read
					VISIT 11	04NOV2020	16:19	71.06592	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22	76.37296	Double Read
					VISIT 4	05JAN2016	15:49	80.01712	Double Read
					VISIT 6	11MAY2016	16:27	73.89536	Double Read
					VISIT 7	16NOV2016	16:29	74.336	Double Read
					VISIT 8	15NOV2017	16:31	76.97088	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	04NOV2020	16:19	67.24528	Double Read
					VISIT 3A	17NOV2015	16:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	19AUG2015	16:32	lower	Double Read
					VISIT 3A	17NOV2015	16:22	lower	Double Read
					VISIT 4	05JAN2016	15:49	lower	Double Read
					VISIT 6	11MAY2016	16:27	lower	Double Read
					VISIT 7	16NOV2016	16:29	lower	Double Read
					VISIT 8	15NOV2017	16:31	lower	Double Read
					VISIT 11	04NOV2020	16:19	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		VISIT 11	04NOV2020	16:19		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	19AUG2015	16:32	equal	Double Read
					VISIT 3A	17NOV2015	16:22	lower	Double Read
					VISIT 4	05JAN2016	15:49	equal	Double Read
					VISIT 6	11MAY2016	16:27	equal	Double Read
					VISIT 7	16NOV2016	16:29	lower	Double Read
					VISIT 8	15NOV2017	16:31	lower	Double Read
					VISIT 11	04NOV2020	16:19	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22	4.71300152879	Double Read
					VISIT 4	05JAN2016	15:49	2.17994224562	Double Read
					VISIT 6	11MAY2016	16:27	10.8148122983	Double Read
					VISIT 7	16NOV2016	16:29	7.50645150331	Double Read
					VISIT 8	15NOV2017	16:31	4.02015967385	Double Read
					VISIT 11	04NOV2020	16:19	3.26991676576	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22	8.49931034484	Double Read
					VISIT 4	05JAN2016	15:49	3.58740275183	Double Read
					VISIT 6	11MAY2016	16:27	8.50946832003	Double Read
					VISIT 7	16NOV2016	16:29	10.7921386105	Double Read
					VISIT 8	15NOV2017	16:31	8.12524545609	Double Read
					VISIT 11	04NOV2020	16:19	5.52629862409	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22	4.62806862578	Double Read
					VISIT 4	05JAN2016	15:49	9.42148462716	Double Read
					VISIT 6	11MAY2016	16:27	9.39452352641	Double Read
					VISIT 7	16NOV2016	16:29	6.52670630202	Double Read
					VISIT 8	15NOV2017	16:31	11.3243893324	Double Read
					VISIT 11	04NOV2020	16:19	3.50489553253	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	19AUG2015	16:32	9525.0	Double Read
					VISIT 3A	17NOV2015	16:22	9407.5	Double Read
					VISIT 4	05JAN2016	15:49	9659.0	Double Read
					VISIT 6	11MAY2016	16:27	9865.0	Double Read
					VISIT 7	16NOV2016	16:29	9216.0	Double Read
					VISIT 8	15NOV2017	16:31	8976.0	Double Read
					VISIT 11	04NOV2020	16:19	8884.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	19AUG2015	16:32	10743.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	17NOV2015	16:22	9726.0	Double Read
					VISIT 4	05JAN2016	15:49	10741.0	Double Read
					VISIT 6	11MAY2016	16:27	11067.0	Double Read
					VISIT 7	16NOV2016	16:29	8849.5	Double Read
					VISIT 8	15NOV2017	16:31	7668.5	Double Read
					VISIT 11	04NOV2020	16:19	10932.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	19AUG2015	16:32		Double Read
					VISIT 3A	17NOV2015	16:22		Double Read
					VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	19AUG2015	16:32	13093.5	Double Read
					VISIT 3A	17NOV2015	16:22	13369.0	Double Read
					VISIT 4	05JAN2016	15:49	12969.0	Double Read
					VISIT 6	11MAY2016	16:27	13500.0	Double Read
					VISIT 7	16NOV2016	16:29	11904.5	Double Read
					VISIT 8	15NOV2017	16:31	11491.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	04NOV2020	16:19	12844.0	Double Read
					VISIT 3A	17NOV2015	16:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0147 Age=44 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	05JAN2016	15:49		Double Read
					VISIT 6	11MAY2016	16:27		Double Read
					VISIT 7	16NOV2016	16:29		Double Read
					VISIT 8	15NOV2017	16:31		Double Read
					VISIT 11	04NOV2020	16:19		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	21OCT2015	16:50	3	Double Read
					VISIT 3A	11JAN2016	16:15	3	Double Read
					VISIT 4	24FEB2016	17:18	3	Double Read
					VISIT 6	20JUN2016	16:44	3	Double Read
					VISIT 7	14DEC2016	16:26	3	Double Read
					VISIT 8	13DEC2017	16:10	3	Double Read
					VISIT 11	08FEB2021	16:18	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	21OCT2015	16:50	2	Double Read
					VISIT 3A	11JAN2016	16:15	2	Double Read
					VISIT 4	24FEB2016	17:18	2	Double Read
					VISIT 6	20JUN2016	16:44	2	Double Read
					VISIT 7	14DEC2016	16:26	2	Double Read
					VISIT 8	13DEC2017	16:10	2	Double Read
					VISIT 11	08FEB2021	16:18	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	21OCT2015	16:50	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	11JAN2016	16:15	N	Double Read
					VISIT 4	24FEB2016	17:18	N	Double Read
					VISIT 6	20JUN2016	16:44	N	Double Read
					VISIT 7	14DEC2016	16:26	N	Double Read
					VISIT 8	13DEC2017	16:10	N	Double Read
					VISIT 11	08FEB2021	16:18	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	21OCT2015	16:50	N	Double Read
					VISIT 3A	11JAN2016	16:15	N	Double Read
					VISIT 4	24FEB2016	17:18	N	Double Read
					VISIT 6	20JUN2016	16:44	N	Double Read
					VISIT 7	14DEC2016	16:26	N	Double Read
					VISIT 8	13DEC2017	16:10	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	08FEB2021	16:18	N	Double Read
					Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
					Baseline	21OCT2015	16:50	Y	Double Read
					VISIT 3A	11JAN2016	16:15	Y	Double Read
					VISIT 4	24FEB2016	17:18	Y	Double Read
					VISIT 6	20JUN2016	16:44	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	14DEC2016	16:26	Y	Double Read
					VISIT 8	13DEC2017	16:10	N	Double Read
					VISIT 11	08FEB2021	16:18	N	Double Read
					Baseline	21OCT2015	16:50	N	Double Read
					VISIT 3A	11JAN2016	16:15	N	Double Read
					VISIT 4	24FEB2016	17:18	N	Double Read
					VISIT 6	20JUN2016	16:44	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	14DEC2016	16:26	N	Double Read
					VISIT 8	13DEC2017	16:10	N	Double Read
					VISIT 11	08FEB2021	16:18	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	21OCT2015	16:50	N	Double Read
					VISIT 3A	11JAN2016	16:15	N	Double Read
					VISIT 4	24FEB2016	17:18	N	Double Read
					VISIT 6	20JUN2016	16:44	N	Double Read
					VISIT 7	14DEC2016	16:26	N	Double Read
					VISIT 8	13DEC2017	16:10	N	Double Read
					VISIT 11	08FEB2021	16:18	N	Double Read
Fracture	5_S		General		Baseline	21OCT2015	16:50	N	Double Read
					VISIT 3A	11JAN2016	16:15	N	Double Read
					VISIT 4	24FEB2016	17:18	N	Double Read
					VISIT 6	20JUN2016	16:44	N	Double Read
					VISIT 7	14DEC2016	16:26	N	Double Read
					VISIT 8	13DEC2017	16:10	N	Double Read
					VISIT 11	08FEB2021	16:18	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	21OCT2015	16:50	11.685	Double Read
					VISIT 3A	11JAN2016	16:15	15.375	Double Read
					VISIT 4	24FEB2016	17:18	15.375	Double Read
					VISIT 6	20JUN2016	16:44	15.705	Double Read
					VISIT 7	14DEC2016	16:26	13.23	Double Read
					VISIT 8	13DEC2017	16:10	12.355	Double Read
					VISIT 11	08FEB2021	16:18	13.59	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	21OCT2015	16:50	15.62	Double Read
					VISIT 3A	11JAN2016	16:15	17.355	Double Read
					VISIT 4	24FEB2016	17:18	16.83	Double Read
					VISIT 6	20JUN2016	16:44	16.92	Double Read
					VISIT 7	14DEC2016	16:26	16.59	Double Read
					VISIT 8	13DEC2017	16:10	16.62	Double Read
					VISIT 11	08FEB2021	16:18	16.135	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	21OCT2015	16:50	9.179995	Double Read
					VISIT 3A	11JAN2016	16:15	9.12287	Double Read
					VISIT 4	24FEB2016	17:18	9.33079	Double Read
					VISIT 6	20JUN2016	16:44	8.80985	Double Read
					VISIT 7	14DEC2016	16:26	9.082085	Double Read
					VISIT 8	13DEC2017	16:10	8.62599	Double Read
					VISIT 11	08FEB2021	16:18	5.443525	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	21OCT2015	16:50	12.0182	Double Read
					VISIT 3A	11JAN2016	16:15	12.715	Double Read
					VISIT 4	24FEB2016	17:18	12.0916	Double Read
					VISIT 6	20JUN2016	16:44	12.43455	Double Read
					VISIT 7	14DEC2016	16:26	11.40795	Double Read
					VISIT 8	13DEC2017	16:10	13.1637	Double Read
					VISIT 11	08FEB2021	16:18	13.50445	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	21OCT2015	16:50	N	Double Read
					VISIT 3A	11JAN2016	16:15	N	Double Read
					VISIT 4	24FEB2016	17:18	N	Double Read
					VISIT 6	20JUN2016	16:44	N	Double Read
					VISIT 7	14DEC2016	16:26	N	Double Read
					VISIT 8	13DEC2017	16:10	N	Double Read
					VISIT 11	08FEB2021	16:18	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	21OCT2015	16:50	N	Double Read
					VISIT 3A	11JAN2016	16:15	N	Double Read
					VISIT 4	24FEB2016	17:18	N	Double Read
					VISIT 6	20JUN2016	16:44	N	Double Read
					VISIT 7	14DEC2016	16:26	N	Double Read
					VISIT 8	13DEC2017	16:10	N	Double Read
					VISIT 11	08FEB2021	16:18	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	21OCT2015	16:50	N	Double Read
					VISIT 3A	11JAN2016	16:15	N	Double Read
					VISIT 4	24FEB2016	17:18	N	Double Read
					VISIT 6	20JUN2016	16:44	N	Double Read
					VISIT 7	14DEC2016	16:26	N	Double Read
					VISIT 8	13DEC2017	16:10	N	Double Read
					VISIT 11	08FEB2021	16:18	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	21OCT2015	16:50	N	Double Read
					VISIT 3A	11JAN2016	16:15	N	Double Read
					VISIT 4	24FEB2016	17:18	N	Double Read
					VISIT 6	20JUN2016	16:44	N	Double Read
					VISIT 7	14DEC2016	16:26	N	Double Read
					VISIT 8	13DEC2017	16:10	N	Double Read
					VISIT 11	08FEB2021	16:18	N	Double Read
Normal lordotic LS	5_S		General		Baseline	21OCT2015	16:50	Y	Double Read
					VISIT 3A	11JAN2016	16:15	Y	Double Read
					VISIT 4	24FEB2016	17:18	Y	Double Read
					VISIT 6	20JUN2016	16:44	Y	Double Read
					VISIT 7	14DEC2016	16:26	Y	Double Read
					VISIT 8	13DEC2017	16:10	Y	Double Read
					VISIT 11	08FEB2021	16:18	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	21OCT2015	16:50	0	Double Read
					VISIT 3A	11JAN2016	16:15	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	24FEB2016	17:18	0	Double Read
					VISIT 6	20JUN2016	16:44	2	Double Read
					VISIT 7	14DEC2016	16:26	0	Double Read
					VISIT 8	13DEC2017	16:10	1	Double Read
					VISIT 11	08FEB2021	16:18	1	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	21OCT2015	16:50	0	Double Read
					VISIT 3A	11JAN2016	16:15	0	Double Read
					VISIT 4	24FEB2016	17:18	0	Double Read
					VISIT 6	20JUN2016	16:44	0	Double Read
					VISIT 7	14DEC2016	16:26	0	Double Read
					VISIT 8	13DEC2017	16:10	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 11	08FEB2021	16:18	0	Double Read
					Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
					Baseline	21OCT2015	16:50	N	Double Read
					VISIT 3A	11JAN2016	16:15	N	Double Read
					VISIT 4	24FEB2016	17:18	N	Double Read
					VISIT 6	20JUN2016	16:44	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	14DEC2016	16:26	N	Double Read
					VISIT 8	13DEC2017	16:10	N	Double Read
					VISIT 11	08FEB2021	16:18	N	Double Read
					Baseline	21OCT2015	16:50	N	Double Read
					VISIT 3A	11JAN2016	16:15	N	Double Read
					VISIT 4	24FEB2016	17:18	N	Double Read
					VISIT 6	20JUN2016	16:44	N	Double Read
					VISIT 7	14DEC2016	16:26	N	Double Read
					VISIT 7	14DEC2016	16:26	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	13DEC2017	16:10	N	Double Read
					VISIT 11	08FEB2021	16:18	N	Double Read
Relevant scoliosis	5_S		General		Baseline	21OCT2015	16:50	N	Double Read
					VISIT 3A	11JAN2016	16:15	N	Double Read
					VISIT 4	24FEB2016	17:18	N	Double Read
					VISIT 6	20JUN2016	16:44	N	Double Read
					VISIT 7	14DEC2016	16:26	N	Double Read
					VISIT 8	13DEC2017	16:10	N	Double Read
					VISIT 11	08FEB2021	16:18	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	21OCT2015	16:50	N	Double Read
					VISIT 3A	11JAN2016	16:15	N	Double Read
					VISIT 4	24FEB2016	17:18	N	Double Read
					VISIT 6	20JUN2016	16:44	N	Double Read
					VISIT 7	14DEC2016	16:26	N	Double Read
					VISIT 8	13DEC2017	16:10	N	Double Read
					VISIT 11	08FEB2021	16:18	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	21OCT2015	16:50	N	Double Read
					VISIT 3A	11JAN2016	16:15	N	Double Read
					VISIT 4	24FEB2016	17:18	N	Double Read
					VISIT 6	20JUN2016	16:44	N	Double Read
					VISIT 7	14DEC2016	16:26	N	Double Read
					VISIT 8	13DEC2017	16:10	N	Double Read
					VISIT 11	08FEB2021	16:18	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	21OCT2015	16:50	75.62048	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	11JAN2016	16:15	77.22208	Double Read
					VISIT 4	24FEB2016	17:18	75.96752	Double Read
					VISIT 6	20JUN2016	16:44	75.24736	Double Read
					VISIT 7	14DEC2016	16:26	73.96288	Double Read
					VISIT 8	13DEC2017	16:10	84.0184	Double Read
					VISIT 11	08FEB2021	16:18	70.27856	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 11	08FEB2021	16:18		Double Read
					Baseline	21OCT2015	16:50	86.53792	Double Read
					VISIT 3A	11JAN2016	16:15	87.71344	Double Read
					VISIT 4	24FEB2016	17:18	85.22704	Double Read
					VISIT 6	20JUN2016	16:44	86.21776	Double Read
					VISIT 7	14DEC2016	16:26	83.6544	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	13DEC2017	16:10	79.30048	Double Read
					VISIT 11	08FEB2021	16:18	78.33584	Double Read
					Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 8	13DEC2017	16:10		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	08FEB2021	16:18		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	21OCT2015	16:50	lower	Double Read
					VISIT 3A	11JAN2016	16:15	lower	Double Read
					VISIT 4	24FEB2016	17:18	lower	Double Read
					VISIT 6	20JUN2016	16:44	lower	Double Read
					VISIT 7	14DEC2016	16:26	lower	Double Read
					VISIT 8	13DEC2017	16:10	lower	Double Read
					VISIT 11	08FEB2021	16:18	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	21OCT2015	16:50	9.30864616953	Double Read
					VISIT 3A	11JAN2016	16:15	11.7687786649	Double Read
					VISIT 4	24FEB2016	17:18	7.59947681332	Double Read
					VISIT 6	20JUN2016	16:44	10.3221810769	Double Read
					VISIT 7	14DEC2016	16:26	11.182836759	Double Read
					VISIT 8	13DEC2017	16:10	6.88239850518	Double Read
					VISIT 11	08FEB2021	16:18	6.20010191949	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	21OCT2015	16:50	5.7660064549	Double Read
					VISIT 3A	11JAN2016	16:15	11.1931713946	Double Read
					VISIT 4	24FEB2016	17:18	9.82957023951	Double Read
					VISIT 6	20JUN2016	16:44	19.9029726516	Double Read
					VISIT 7	14DEC2016	16:26	4.87514863258	Double Read
					VISIT 8	13DEC2017	16:10	12.7824019025	Double Read
					VISIT 11	08FEB2021	16:18	8.8152811279	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	21OCT2015	16:50	16000.5	Double Read
					VISIT 3A	11JAN2016	16:15	16362.5	Double Read
					VISIT 4	24FEB2016	17:18	16274.5	Double Read
					VISIT 6	20JUN2016	16:44	17145.0	Double Read
					VISIT 7	14DEC2016	16:26	15467.5	Double Read
					VISIT 8	13DEC2017	16:10	13680.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0148 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 11	08FEB2021	16:18	13604.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	21OCT2015	16:50	19412.5	Double Read
					VISIT 3A	11JAN2016	16:15	20966.5	Double Read
					VISIT 4	24FEB2016	17:18	19480.5	Double Read
					VISIT 6	20JUN2016	16:44	20831.0	Double Read
					VISIT 7	14DEC2016	16:26	19754.0	Double Read
					VISIT 8	13DEC2017	16:10	19751.0	Double Read
					VISIT 11	08FEB2021	16:18	20375.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	21OCT2015	16:50		Double Read
					VISIT 3A	11JAN2016	16:15		Double Read
					VISIT 4	24FEB2016	17:18		Double Read
					VISIT 6	20JUN2016	16:44		Double Read
					VISIT 7	14DEC2016	16:26		Double Read
					VISIT 8	13DEC2017	16:10		Double Read
					VISIT 11	08FEB2021	16:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	01DEC2015	17:56	3	Double Read
					VISIT 3A	29FEB2016	16:16	2	Double Read
					VISIT 4	13APR2016	15:56	3	Double Read
					VISIT 6	14SEP2016	16:40	2	Double Read
					VISIT 7	15MAR2017	17:03	3	Double Read
					VISIT 8	14MAR2018	16:09	2	Double Read
					VISIT 11	24FEB2021	16:10	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	01DEC2015	17:56	4	Double Read
					VISIT 3A	29FEB2016	16:16	3	Double Read
					VISIT 4	13APR2016	15:56	4	Double Read
					VISIT 6	14SEP2016	16:40	4	Double Read
					VISIT 7	15MAR2017	17:03	4	Double Read
					VISIT 8	14MAR2018	16:09	4	Double Read
					VISIT 11	24FEB2021	16:10	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01DEC2015	17:56	2	Double Read
					VISIT 3A	29FEB2016	16:16	2	Double Read
					VISIT 4	13APR2016	15:56	3	Double Read
					VISIT 6	14SEP2016	16:40	2	Double Read
					VISIT 7	15MAR2017	17:03	3	Double Read
					VISIT 8	14MAR2018	16:09	2	Double Read
					VISIT 11	24FEB2021	16:10	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
					VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	01DEC2015	17:56	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
					VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
					VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 11	24FEB2021	16:10	N	Double Read
					Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
					VISIT 7	15MAR2017	17:03	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read
					Baseline	01DEC2015	17:56	Y	Double Read
					VISIT 3A	29FEB2016	16:16	Y	Double Read
					VISIT 4	13APR2016	15:56	Y	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	Y	Double Read
					VISIT 11	24FEB2021	16:10	Y	Double Read
					Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
					VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read
Fracture	4_5		General		Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
					VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	01DEC2015	17:56	14.605	Double Read
					VISIT 3A	29FEB2016	16:16	15.05	Double Read
					VISIT 4	13APR2016	15:56	15.215	Double Read
					VISIT 6	14SEP2016	16:40	15.15	Double Read
					VISIT 7	15MAR2017	17:03	15.68	Double Read
					VISIT 8	14MAR2018	16:09	14.365	Double Read
					VISIT 11	24FEB2021	16:10	14.75	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	01DEC2015	17:56	12.205	Double Read
					VISIT 3A	29FEB2016	16:16	12.275	Double Read
					VISIT 4	13APR2016	15:56	11.55	Double Read
					VISIT 6	14SEP2016	16:40	13.495	Double Read
					VISIT 7	15MAR2017	17:03	11.15	Double Read
					VISIT 8	14MAR2018	16:09	9.7	Double Read
					VISIT 11	24FEB2021	16:10	11.12	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	01DEC2015	17:56	12.885	Double Read
					VISIT 3A	29FEB2016	16:16	14.575	Double Read
					VISIT 4	13APR2016	15:56	13.64	Double Read
					VISIT 6	14SEP2016	16:40	13.39	Double Read
					VISIT 7	15MAR2017	17:03	13.91	Double Read
					VISIT 8	14MAR2018	16:09	13.55	Double Read
					VISIT 11	24FEB2021	16:10	13.69	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	01DEC2015	17:56	9.615915	Double Read
					VISIT 3A	29FEB2016	16:16	9.770795	Double Read
					VISIT 4	13APR2016	15:56	10.64995	Double Read
					VISIT 6	14SEP2016	16:40	10.798415	Double Read
					VISIT 7	15MAR2017	17:03	9.337025	Double Read
					VISIT 8	14MAR2018	16:09	9.111165	Double Read
					VISIT 11	24FEB2021	16:10	9.62486	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	01DEC2015	17:56	9.459335	Double Read
					VISIT 3A	29FEB2016	16:16	9.78386	Double Read
					VISIT 4	13APR2016	15:56	9.279355	Double Read
					VISIT 6	14SEP2016	16:40	9.42336	Double Read
					VISIT 7	15MAR2017	17:03	9.22924	Double Read
					VISIT 8	14MAR2018	16:09	8.12348	Double Read
					VISIT 11	24FEB2021	16:10	6.598915	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	01DEC2015	17:56	11.04325	Double Read
					VISIT 3A	29FEB2016	16:16	11.61786	Double Read
					VISIT 4	13APR2016	15:56	10.707	Double Read
					VISIT 6	14SEP2016	16:40	10.7722	Double Read
					VISIT 7	15MAR2017	17:03	10.53076	Double Read
					VISIT 8	14MAR2018	16:09	10.265895	Double Read
					VISIT 11	24FEB2021	16:10	10.26427	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
					VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
					VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
					VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
					VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
					VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
					VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read
Normal lordotic LS	4_5		General		Baseline	01DEC2015	17:56	Y	Double Read
					VISIT 3A	29FEB2016	16:16	Y	Double Read
					VISIT 4	13APR2016	15:56	Y	Double Read
					VISIT 6	14SEP2016	16:40	Y	Double Read
					VISIT 7	15MAR2017	17:03	Y	Double Read
					VISIT 8	14MAR2018	16:09	Y	Double Read
					VISIT 11	24FEB2021	16:10	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	01DEC2015	17:56	0	Double Read
					VISIT 3A	29FEB2016	16:16	0	Double Read
					VISIT 4	13APR2016	15:56	0	Double Read
					VISIT 6	14SEP2016	16:40	0	Double Read
					VISIT 7	15MAR2017	17:03	0	Double Read
					VISIT 8	14MAR2018	16:09	0	Double Read
					VISIT 11	24FEB2021	16:10	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	01DEC2015	17:56	2	Double Read
					VISIT 3A	29FEB2016	16:16	2	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 4	13APR2016	15:56	2	Double Read
					VISIT 6	14SEP2016	16:40	2	Double Read
					VISIT 7	15MAR2017	17:03	2	Double Read
					VISIT 8	14MAR2018	16:09	2	Double Read
					VISIT 11	24FEB2021	16:10	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01DEC2015	17:56	0	Double Read
					VISIT 3A	29FEB2016	16:16	0	Double Read
					VISIT 4	13APR2016	15:56	0	Double Read
					VISIT 6	14SEP2016	16:40	0	Double Read
					VISIT 7	15MAR2017	17:03	0	Double Read
					VISIT 8	14MAR2018	16:09	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 11	24FEB2021	16:10	0	Double Read
					Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
					VISIT 7	15MAR2017	17:03	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read
					Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read
					Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
					VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read
Relevant scoliosis	4_5		General		Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
					VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
					VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
					VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01DEC2015	17:56	N	Double Read
					VISIT 3A	29FEB2016	16:16	N	Double Read
					VISIT 4	13APR2016	15:56	N	Double Read
					VISIT 6	14SEP2016	16:40	N	Double Read
					VISIT 7	15MAR2017	17:03	N	Double Read
					VISIT 8	14MAR2018	16:09	N	Double Read
					VISIT 11	24FEB2021	16:10	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	01DEC2015	17:56	77.7296	Double Read
					VISIT 3A	29FEB2016	16:16	77.72416	Double Read
					VISIT 4	13APR2016	15:56	76.0384	Double Read
					VISIT 6	14SEP2016	16:40	74.92352	Double Read
					VISIT 7	15MAR2017	17:03	74.46464	Double Read
					VISIT 8	14MAR2018	16:09	74.35488	Double Read
					VISIT 11	24FEB2021	16:10	70.16352	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	01DEC2015	17:56	74.77312	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	29FEB2016	16:16	76.9624	Double Read
					VISIT 4	13APR2016	15:56	72.60944	Double Read
					VISIT 6	14SEP2016	16:40	76.12848	Double Read
					VISIT 7	15MAR2017	17:03	74.82032	Double Read
					VISIT 8	14MAR2018	16:09	72.20752	Double Read
					VISIT 11	24FEB2021	16:10	70.94368	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	01DEC2015	17:56	85.43408	Double Read
					VISIT 3A	29FEB2016	16:16	80.68864	Double Read
					VISIT 4	13APR2016	15:56	80.65504	Double Read
					VISIT 6	14SEP2016	16:40	79.3224	Double Read
					VISIT 7	15MAR2017	17:03	77.98544	Double Read
					VISIT 8	14MAR2018	16:09	77.1072	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	24FEB2021	16:10	69.94192	Double Read
					VISIT 3A	29FEB2016	16:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	01DEC2015	17:56	lower	Double Read
					VISIT 3A	29FEB2016	16:16	lower	Double Read
					VISIT 4	13APR2016	15:56	lower	Double Read
					VISIT 6	14SEP2016	16:40	lower	Double Read
					VISIT 7	15MAR2017	17:03	lower	Double Read
					VISIT 8	14MAR2018	16:09	lower	Double Read
					VISIT 11	24FEB2021	16:10	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		VISIT 11	24FEB2021	16:10		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	01DEC2015	17:56	lower	Double Read
					VISIT 3A	29FEB2016	16:16	lower	Double Read
					VISIT 4	13APR2016	15:56	lower	Double Read
					VISIT 6	14SEP2016	16:40	lower	Double Read
					VISIT 7	15MAR2017	17:03	lower	Double Read
					VISIT 8	14MAR2018	16:09	lower	Double Read
					VISIT 11	24FEB2021	16:10	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	01DEC2015	17:56	13.790589434	Double Read
					VISIT 3A	29FEB2016	16:16	12.938107694	Double Read
					VISIT 4	13APR2016	15:56	10.859283166	Double Read
					VISIT 6	14SEP2016	16:40	10.823115338	Double Read
					VISIT 7	15MAR2017	17:03	8.6017394258	Double Read
					VISIT 8	14MAR2018	16:09	9.1598709019	Double Read
					VISIT 11	24FEB2021	16:10	9.7955970783	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	01DEC2015	17:56	4.8132699167	Double Read
					VISIT 3A	29FEB2016	16:16	6	Double Read
					VISIT 4	13APR2016	15:56	10.852801087	Double Read
					VISIT 6	14SEP2016	16:40	2	Double Read
					VISIT 7	15MAR2017	17:03	8.0233259724	Double Read
					VISIT 8	14MAR2018	16:09	8	Double Read
					VISIT 11	24FEB2021	16:10	7.8650586037	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	01DEC2015	17:56	9.7409954136	Double Read
					VISIT 3A	29FEB2016	16:16	6.9159639884	Double Read
					VISIT 4	13APR2016	15:56	13.351452352	Double Read
					VISIT 6	14SEP2016	16:40	10.952301681	Double Read
					VISIT 7	15MAR2017	17:03	8.8937659249	Double Read
					VISIT 8	14MAR2018	16:09	14.427246475	Double Read
					VISIT 11	24FEB2021	16:10	10.741987429	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	01DEC2015	17:56	12057.5	Double Read
					VISIT 3A	29FEB2016	16:16	12460.0	Double Read
					VISIT 4	13APR2016	15:56	11637.0	Double Read
					VISIT 6	14SEP2016	16:40	12461.5	Double Read
					VISIT 7	15MAR2017	17:03	12573.0	Double Read
					VISIT 8	14MAR2018	16:09	11737.5	Double Read
					VISIT 11	24FEB2021	16:10	11859.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	01DEC2015	17:56	11234.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	29FEB2016	16:16	11716.0	Double Read
					VISIT 4	13APR2016	15:56	10936.5	Double Read
					VISIT 6	14SEP2016	16:40	12101.0	Double Read
					VISIT 7	15MAR2017	17:03	10649.0	Double Read
					VISIT 8	14MAR2018	16:09	9372.0	Double Read
					VISIT 11	24FEB2021	16:10	9272.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read
					VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	01DEC2015	17:56	12693.5	Double Read
					VISIT 3A	29FEB2016	16:16	13033.5	Double Read
					VISIT 4	13APR2016	15:56	12802.0	Double Read
					VISIT 6	14SEP2016	16:40	13386.0	Double Read
					VISIT 7	15MAR2017	17:03	13777.0	Double Read
					VISIT 8	14MAR2018	16:09	12068.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	01DEC2015	17:56		Double Read
					VISIT 3A	29FEB2016	16:16		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0149 Age=51 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	13APR2016	15:56		Double Read
					VISIT 6	14SEP2016	16:40		Double Read
					VISIT 7	15MAR2017	17:03		Double Read
					VISIT 8	14MAR2018	16:09		Double Read
					VISIT 11	24FEB2021	16:10		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0150 Age=45 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	02FEB2016	16:15	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	02FEB2016	16:15	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	02FEB2016	16:15	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	02FEB2016	16:15	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	02FEB2016	16:15	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	02FEB2016	16:15	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	02FEB2016	16:15	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	02FEB2016	16:15	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	02FEB2016	16:15	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	02FEB2016	16:15	N	Double Read
Fracture	4_5		General		Baseline	02FEB2016	16:15	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	02FEB2016	16:15	12.195	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	02FEB2016	16:15	14.26	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	02FEB2016	16:15	12.81	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0150 Age=45 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	02FEB2016	16:15	10.45595	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	02FEB2016	16:15	11.5001	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	02FEB2016	16:15	10.87365	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	02FEB2016	16:15	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	02FEB2016	16:15	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	02FEB2016	16:15	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	02FEB2016	16:15	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	02FEB2016	16:15	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	02FEB2016	16:15	N	Double Read
Normal lordotic LS	4_5		General		Baseline	02FEB2016	16:15	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	02FEB2016	16:15	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	02FEB2016	16:15	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0150 Age=45 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	02FEB2016	16:15	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	02FEB2016	16:15	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	02FEB2016	16:15	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	02FEB2016	16:15	N	Double Read
Relevant scoliosis	4_5		General		Baseline	02FEB2016	16:15	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	02FEB2016	16:15	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	02FEB2016	16:15	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	02FEB2016	16:15	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	02FEB2016	16:15		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	02FEB2016	16:15	65.25216	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	02FEB2016	16:15		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	02FEB2016	16:15		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	02FEB2016	16:15	71.53776	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	02FEB2016	16:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0150 Age=45 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	02FEB2016	16:15		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	02FEB2016	16:15	63.40864	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	02FEB2016	16:15		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	02FEB2016	16:15		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	02FEB2016	16:15		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	02FEB2016	16:15		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	02FEB2016	16:15		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	02FEB2016	16:15	higher	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	02FEB2016	16:15		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	02FEB2016	16:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0150 Age=45 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	02FEB2016	16:15	higher	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	02FEB2016	16:15		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	02FEB2016	16:15		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	02FEB2016	16:15		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	02FEB2016	16:15		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	02FEB2016	16:15		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	02FEB2016	16:15	7.4287956514	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	02FEB2016	16:15		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	02FEB2016	16:15		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	02FEB2016	16:15	14.3140479021	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	02FEB2016	16:15		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	02FEB2016	16:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0150 Age=45 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	02FEB2016	16:15	5.29451333447	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	02FEB2016	16:15		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	02FEB2016	16:15		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	02FEB2016	16:15	9500.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	02FEB2016	16:15		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	02FEB2016	16:15		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	02FEB2016	16:15	11369.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	02FEB2016	16:15		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	02FEB2016	16:15		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	02FEB2016	16:15	11712.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	02FEB2016	16:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	02MAR2016	15:34	2	Double Read
					VISIT 3A	06JUN2016	16:52	3	Double Read
					VISIT 4	13JUL2016	16:17	3	Double Read
					VISIT 6	30NOV2016	16:01	3	Double Read
					VISIT 7	31MAY2017	17:01	3	Double Read
					VISIT 8	02MAY2018	16:33	3	Double Read
					VISIT 11	12MAY2021	16:02	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	15:34	3	Double Read
					VISIT 3A	06JUN2016	16:52	3	Double Read
					VISIT 4	13JUL2016	16:17	3	Double Read
					VISIT 6	30NOV2016	16:01	3	Double Read
					VISIT 7	31MAY2017	17:01	3	Double Read
					VISIT 8	02MAY2018	16:33	3	Double Read
					VISIT 11	12MAY2021	16:02	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	02MAR2016	15:34	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	06JUN2016	16:52	N	Double Read
					VISIT 4	13JUL2016	16:17	N	Double Read
					VISIT 6	30NOV2016	16:01	N	Double Read
					VISIT 7	31MAY2017	17:01	N	Double Read
					VISIT 8	02MAY2018	16:33	N	Double Read
					VISIT 11	12MAY2021	16:02	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	15:34	N	Double Read
					VISIT 3A	06JUN2016	16:52	N	Double Read
					VISIT 4	13JUL2016	16:17	N	Double Read
					VISIT 6	30NOV2016	16:01	N	Double Read
					VISIT 7	31MAY2017	17:01	N	Double Read
					VISIT 8	02MAY2018	16:33	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	12MAY2021	16:02	N	Double Read
					Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
					Baseline	02MAR2016	15:34	Y	Double Read
					VISIT 3A	06JUN2016	16:52	N	Double Read
					VISIT 4	13JUL2016	16:17	Y	Double Read
					VISIT 6	30NOV2016	16:01	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	31MAY2017	17:01	Y	Double Read
					VISIT 8	02MAY2018	16:33	Y	Double Read
					VISIT 11	12MAY2021	16:02	Y	Double Read
					Baseline	02MAR2016	15:34	Y	Double Read
					VISIT 3A	06JUN2016	16:52	N	Double Read
					VISIT 4	13JUL2016	16:17	Y	Double Read
					VISIT 6	30NOV2016	16:01	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	31MAY2017	17:01	Y	Double Read
					VISIT 8	02MAY2018	16:33	Y	Double Read
					VISIT 11	12MAY2021	16:02	Y	Double Read
Extradiscal fluid collection	5_S		General		Baseline	02MAR2016	15:34	N	Double Read
					VISIT 3A	06JUN2016	16:52	N	Double Read
					VISIT 4	13JUL2016	16:17	N	Double Read
					VISIT 6	30NOV2016	16:01	N	Double Read
					VISIT 7	31MAY2017	17:01	N	Double Read
					VISIT 8	02MAY2018	16:33	N	Double Read
					VISIT 11	12MAY2021	16:02	N	Double Read
Fracture	5_S		General		Baseline	02MAR2016	15:34	N	Double Read
					VISIT 3A	06JUN2016	16:52	N	Double Read
					VISIT 4	13JUL2016	16:17	N	Double Read
					VISIT 6	30NOV2016	16:01	N	Double Read
					VISIT 7	31MAY2017	17:01	N	Double Read
					VISIT 8	02MAY2018	16:33	N	Double Read
					VISIT 11	12MAY2021	16:02	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	02MAR2016	15:34	14.525	Double Read
					VISIT 3A	06JUN2016	16:52	14.875	Double Read
					VISIT 4	13JUL2016	16:17	15.11	Double Read
					VISIT 6	30NOV2016	16:01	14.145	Double Read
					VISIT 7	31MAY2017	17:01	15.66	Double Read
					VISIT 8	02MAY2018	16:33	15.17	Double Read
					VISIT 11	12MAY2021	16:02	13.61	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	02MAR2016	15:34	15.21	Double Read
					VISIT 3A	06JUN2016	16:52	16.46	Double Read
					VISIT 4	13JUL2016	16:17	17.595	Double Read
					VISIT 6	30NOV2016	16:01	16.795	Double Read
					VISIT 7	31MAY2017	17:01	17.815	Double Read
					VISIT 8	02MAY2018	16:33	16.935	Double Read
					VISIT 11	12MAY2021	16:02	17.26	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	02MAR2016	15:34	8.84991	Double Read
					VISIT 3A	06JUN2016	16:52	7.702555	Double Read
					VISIT 4	13JUL2016	16:17	9.47137	Double Read
					VISIT 6	30NOV2016	16:01	8.767345	Double Read
					VISIT 7	31MAY2017	17:01	8.80439	Double Read
					VISIT 8	02MAY2018	16:33	9.60488	Double Read
					VISIT 11	12MAY2021	16:02	8.69816	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	02MAR2016	15:34	11.17175	Double Read
					VISIT 3A	06JUN2016	16:52	11.0349	Double Read
					VISIT 4	13JUL2016	16:17	11.78445	Double Read
					VISIT 6	30NOV2016	16:01	11.86185	Double Read
					VISIT 7	31MAY2017	17:01	12.16095	Double Read
					VISIT 8	02MAY2018	16:33	11.0726	Double Read
					VISIT 11	12MAY2021	16:02	12.78635	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	02MAR2016	15:34	N	Double Read
					VISIT 3A	06JUN2016	16:52	N	Double Read
					VISIT 4	13JUL2016	16:17	N	Double Read
					VISIT 6	30NOV2016	16:01	N	Double Read
					VISIT 7	31MAY2017	17:01	N	Double Read
					VISIT 8	02MAY2018	16:33	N	Double Read
					VISIT 11	12MAY2021	16:02	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	15:34	N	Double Read
					VISIT 3A	06JUN2016	16:52	N	Double Read
					VISIT 4	13JUL2016	16:17	N	Double Read
					VISIT 6	30NOV2016	16:01	N	Double Read
					VISIT 7	31MAY2017	17:01	N	Double Read
					VISIT 8	02MAY2018	16:33	N	Double Read
					VISIT 11	12MAY2021	16:02	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	02MAR2016	15:34	N	Double Read
					VISIT 3A	06JUN2016	16:52	N	Double Read
					VISIT 4	13JUL2016	16:17	N	Double Read
					VISIT 6	30NOV2016	16:01	N	Double Read
					VISIT 7	31MAY2017	17:01	N	Double Read
					VISIT 8	02MAY2018	16:33	N	Double Read
					VISIT 11	12MAY2021	16:02	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	15:34	N	Double Read
					VISIT 3A	06JUN2016	16:52	N	Double Read
					VISIT 4	13JUL2016	16:17	N	Double Read
					VISIT 6	30NOV2016	16:01	N	Double Read
					VISIT 7	31MAY2017	17:01	N	Double Read
					VISIT 8	02MAY2018	16:33	N	Double Read
					VISIT 11	12MAY2021	16:02	N	Double Read
Normal lordotic LS	5_S		General		Baseline	02MAR2016	15:34	Y	Double Read
					VISIT 3A	06JUN2016	16:52	Y	Double Read
					VISIT 4	13JUL2016	16:17	Y	Double Read
					VISIT 6	30NOV2016	16:01	Y	Double Read
					VISIT 7	31MAY2017	17:01	Y	Double Read
					VISIT 8	02MAY2018	16:33	Y	Double Read
					VISIT 11	12MAY2021	16:02	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	02MAR2016	15:34	0	Double Read
					VISIT 3A	06JUN2016	16:52	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	13JUL2016	16:17	0	Double Read
					VISIT 6	30NOV2016	16:01	0	Double Read
					VISIT 7	31MAY2017	17:01	0	Double Read
					VISIT 8	02MAY2018	16:33	0	Double Read
					VISIT 11	12MAY2021	16:02	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	15:34	0	Double Read
					VISIT 3A	06JUN2016	16:52	0	Double Read
					VISIT 4	13JUL2016	16:17	0	Double Read
					VISIT 6	30NOV2016	16:01	0	Double Read
					VISIT 7	31MAY2017	17:01	0	Double Read
					VISIT 8	02MAY2018	16:33	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 11	12MAY2021	16:02	0	Double Read
					Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02	N	Double Read
					Baseline	02MAR2016	15:34	N	Double Read
					VISIT 3A	06JUN2016	16:52	N	Double Read
					VISIT 4	13JUL2016	16:17	N	Double Read
					VISIT 6	30NOV2016	16:01	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	31MAY2017	17:01	N	Double Read
					VISIT 8	02MAY2018	16:33	N	Double Read
					VISIT 11	12MAY2021	16:02	N	Double Read
					Baseline	02MAR2016	15:34	N	Double Read
					VISIT 3A	06JUN2016	16:52	N	Double Read
					VISIT 4	13JUL2016	16:17	N	Double Read
					VISIT 6	30NOV2016	16:01	N	Double Read
					VISIT 7	31MAY2017	17:01	N	Double Read
					VISIT 8	02MAY2018	16:33	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	02MAY2018	16:33	N	Double Read
					VISIT 11	12MAY2021	16:02	N	Double Read
Relevant scoliosis	5_S		General		Baseline	02MAR2016	15:34	N	Double Read
					VISIT 3A	06JUN2016	16:52	N	Double Read
					VISIT 4	13JUL2016	16:17	N	Double Read
					VISIT 6	30NOV2016	16:01	N	Double Read
					VISIT 7	31MAY2017	17:01	N	Double Read
					VISIT 8	02MAY2018	16:33	N	Double Read
					VISIT 11	12MAY2021	16:02	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	02MAR2016	15:34	N	Double Read
					VISIT 3A	06JUN2016	16:52	N	Double Read
					VISIT 4	13JUL2016	16:17	N	Double Read
					VISIT 6	30NOV2016	16:01	N	Double Read
					VISIT 7	31MAY2017	17:01	N	Double Read
					VISIT 8	02MAY2018	16:33	N	Double Read
					VISIT 11	12MAY2021	16:02	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	15:34	N	Double Read
					VISIT 3A	06JUN2016	16:52	N	Double Read
					VISIT 4	13JUL2016	16:17	N	Double Read
					VISIT 6	30NOV2016	16:01	N	Double Read
					VISIT 7	31MAY2017	17:01	N	Double Read
					VISIT 8	02MAY2018	16:33	N	Double Read
					VISIT 11	12MAY2021	16:02	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	02MAR2016	15:34	79.1872	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	06JUN2016	16:52	78.89584	Double Read
					VISIT 4	13JUL2016	16:17	82.12384	Double Read
					VISIT 6	30NOV2016	16:01	77.9072	Double Read
					VISIT 7	31MAY2017	17:01	72.75648	Double Read
					VISIT 8	02MAY2018	16:33	71.07088	Double Read
					VISIT 11	12MAY2021	16:02	70.84432	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	02MAR2016	15:34	76.18816	Double Read
					VISIT 3A	06JUN2016	16:52	75.92208	Double Read
					VISIT 4	13JUL2016	16:17	79.29504	Double Read
					VISIT 6	30NOV2016	16:01	80.46384	Double Read
					VISIT 7	31MAY2017	17:01	74.11184	Double Read
					VISIT 8	02MAY2018	16:33	73.69552	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	12MAY2021	16:02	72.0512	Double Read
					VISIT 3A	06JUN2016	16:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	12MAY2021	16:02		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	02MAR2016	15:34	higher	Double Read
					VISIT 3A	06JUN2016	16:52	equal	Double Read
					VISIT 4	13JUL2016	16:17	equal	Double Read
					VISIT 6	30NOV2016	16:01	equal	Double Read
					VISIT 7	31MAY2017	17:01	higher	Double Read
					VISIT 8	02MAY2018	16:33	equal	Double Read
					VISIT 11	12MAY2021	16:02	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	02MAR2016	15:34	10.246556820	Double Read
					VISIT 3A	06JUN2016	16:52	7.5816748768	Double Read
					VISIT 4	13JUL2016	16:17	2.9712994734	Double Read
					VISIT 6	30NOV2016	16:01	4.7513912009	Double Read
					VISIT 7	31MAY2017	17:01	12.638015967	Double Read
					VISIT 8	02MAY2018	16:33	8.4251401392	Double Read
					VISIT 11	12MAY2021	16:02	9.8125836589	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	02MAR2016	15:34	9.8824120944	Double Read
					VISIT 3A	06JUN2016	16:52	12.032553083	Double Read
					VISIT 4	13JUL2016	16:17	10.667973500	Double Read
					VISIT 6	30NOV2016	16:01	11.619527773	Double Read
					VISIT 7	31MAY2017	17:01	9.2734635637	Double Read
					VISIT 8	02MAY2018	16:33	15.033123832	Double Read
					VISIT 11	12MAY2021	16:02	7.2849396976	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	02MAR2016	15:34	17540.0	Double Read
					VISIT 3A	06JUN2016	16:52	18984.5	Double Read
					VISIT 4	13JUL2016	16:17	16967.0	Double Read
					VISIT 6	30NOV2016	16:01	16474.0	Double Read
					VISIT 7	31MAY2017	17:01	18644.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	02MAY2018	16:33	18075.0	Double Read
					VISIT 11	12MAY2021	16:02	16540.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read
					VISIT 11	12MAY2021	16:02		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	02MAR2016	15:34	18559.5	Double Read
					VISIT 3A	06JUN2016	16:52	21731.5	Double Read
					VISIT 4	13JUL2016	16:17	21672.5	Double Read
					VISIT 6	30NOV2016	16:01	21099.0	Double Read
					VISIT 7	31MAY2017	17:01	21963.0	Double Read
					VISIT 8	02MAY2018	16:33	21204.0	Double Read
					VISIT 11	12MAY2021	16:02	20654.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	02MAR2016	15:34		Double Read
					VISIT 3A	06JUN2016	16:52		Double Read
					VISIT 4	13JUL2016	16:17		Double Read
					VISIT 6	30NOV2016	16:01		Double Read
					VISIT 7	31MAY2017	17:01		Double Read
					VISIT 8	02MAY2018	16:33		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0151 Age=25 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	12MAY2021	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0152 Age=55 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	02MAR2016	16:28	3	Double Read
					VISIT 4	21APR2016	16:43	3	Double Read
					VISIT 6	24AUG2016	16:38	3	Double Read
					VISIT 7	22FEB2017	16:04	3	Double Read
					VISIT 8	07MAR2018	16:40	3	Double Read
					VISIT 11	10MAR2021	16:14	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	16:28	2	Double Read
					VISIT 4	21APR2016	16:43	2	Double Read
					VISIT 6	24AUG2016	16:38	2	Double Read
					VISIT 7	22FEB2017	16:04	3	Double Read
					VISIT 8	07MAR2018	16:40	2	Double Read
					VISIT 11	10MAR2021	16:14	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	02MAR2016	16:28	N	Double Read
					VISIT 4	21APR2016	16:43	N	Double Read
					VISIT 6	24AUG2016	16:38	N	Double Read
					VISIT 7	22FEB2017	16:04	N	Double Read
					VISIT 8	07MAR2018	16:40	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0152 Age=55 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 11	10MAR2021	16:14	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	16:28	N	Double Read
					VISIT 4	21APR2016	16:43	N	Double Read
					VISIT 6	24AUG2016	16:38	N	Double Read
					VISIT 7	22FEB2017	16:04	N	Double Read
					VISIT 8	07MAR2018	16:40	N	Double Read
					VISIT 11	10MAR2021	16:14	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	02MAR2016	16:28	N	Double Read
					VISIT 4	21APR2016	16:43	N	Double Read
					VISIT 6	24AUG2016	16:38	Y	Double Read
					VISIT 7	22FEB2017	16:04	Y	Double Read
					VISIT 8	07MAR2018	16:40	Y	Double Read
					VISIT 11	10MAR2021	16:14	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	16:28	N	Double Read
					VISIT 4	21APR2016	16:43	N	Double Read
					VISIT 6	24AUG2016	16:38	N	Double Read
					VISIT 7	22FEB2017	16:04	N	Double Read
					VISIT 8	07MAR2018	16:40	N	Double Read
					VISIT 11	10MAR2021	16:14	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	02MAR2016	16:28	N	Double Read
					VISIT 4	21APR2016	16:43	N	Double Read
					VISIT 6	24AUG2016	16:38	N	Double Read
					VISIT 7	22FEB2017	16:04	N	Double Read
					VISIT 8	07MAR2018	16:40	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0152 Age=55 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 11	10MAR2021	16:14	N	Double Read
Fracture	5_S		General		Baseline	02MAR2016	16:28	N	Double Read
					VISIT 4	21APR2016	16:43	N	Double Read
					VISIT 6	24AUG2016	16:38	N	Double Read
					VISIT 7	22FEB2017	16:04	N	Double Read
					VISIT 8	07MAR2018	16:40	N	Double Read
					VISIT 11	10MAR2021	16:14	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	02MAR2016	16:28	15.9	Double Read
					VISIT 4	21APR2016	16:43	15.56	Double Read
					VISIT 6	24AUG2016	16:38	15.4	Double Read
					VISIT 7	22FEB2017	16:04	15.11	Double Read
					VISIT 8	07MAR2018	16:40	14.805	Double Read
					VISIT 11	10MAR2021	16:14	15.915	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	02MAR2016	16:28	15.5	Double Read
					VISIT 4	21APR2016	16:43	15.34	Double Read
					VISIT 6	24AUG2016	16:38	15.105	Double Read
					VISIT 7	22FEB2017	16:04	15.105	Double Read
					VISIT 8	07MAR2018	16:40	15.43	Double Read
					VISIT 11	10MAR2021	16:14	16.325	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0152 Age=55 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	02MAR2016	16:28	13.53775	Double Read
					VISIT 4	21APR2016	16:43	12.54215	Double Read
					VISIT 6	24AUG2016	16:38	11.54665	Double Read
					VISIT 7	22FEB2017	16:04	12.36	Double Read
					VISIT 8	07MAR2018	16:40	11.3936	Double Read
					VISIT 11	10MAR2021	16:14	12.34975	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	02MAR2016	16:28	14.6767	Double Read
					VISIT 4	21APR2016	16:43	14.01495	Double Read
					VISIT 6	24AUG2016	16:38	12.81305	Double Read
					VISIT 7	22FEB2017	16:04	12.894	Double Read
					VISIT 8	07MAR2018	16:40	14.09345	Double Read
					VISIT 11	10MAR2021	16:14	13.82105	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	02MAR2016	16:28	N	Double Read
					VISIT 4	21APR2016	16:43	N	Double Read
					VISIT 6	24AUG2016	16:38	N	Double Read
					VISIT 7	22FEB2017	16:04	N	Double Read
					VISIT 8	07MAR2018	16:40	N	Double Read
					VISIT 11	10MAR2021	16:14	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0152 Age=55 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	16:28	N	Double Read
					VISIT 4	21APR2016	16:43	N	Double Read
					VISIT 6	24AUG2016	16:38	N	Double Read
					VISIT 7	22FEB2017	16:04	N	Double Read
					VISIT 8	07MAR2018	16:40	N	Double Read
					VISIT 11	10MAR2021	16:14	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	02MAR2016	16:28	N	Double Read
					VISIT 4	21APR2016	16:43	N	Double Read
					VISIT 6	24AUG2016	16:38	N	Double Read
					VISIT 7	22FEB2017	16:04	N	Double Read
					VISIT 8	07MAR2018	16:40	N	Double Read
					VISIT 11	10MAR2021	16:14	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	16:28	N	Double Read
					VISIT 4	21APR2016	16:43	N	Double Read
					VISIT 6	24AUG2016	16:38	N	Double Read
					VISIT 7	22FEB2017	16:04	N	Double Read
					VISIT 8	07MAR2018	16:40	N	Double Read
					VISIT 11	10MAR2021	16:14	N	Double Read
Normal lordotic LS	5_S		General		Baseline	02MAR2016	16:28	Y	Double Read
					VISIT 4	21APR2016	16:43	Y	Double Read
					VISIT 6	24AUG2016	16:38	Y	Double Read
					VISIT 7	22FEB2017	16:04	Y	Double Read
					VISIT 8	07MAR2018	16:40	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0152 Age=55 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	5_S		General		VISIT 11	10MAR2021	16:14	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	02MAR2016	16:28	0	Double Read
					VISIT 4	21APR2016	16:43	0	Double Read
					VISIT 6	24AUG2016	16:38	0	Double Read
					VISIT 7	22FEB2017	16:04	0	Double Read
					VISIT 8	07MAR2018	16:40	0	Double Read
					VISIT 11	10MAR2021	16:14	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	16:28	0	Double Read
					VISIT 4	21APR2016	16:43	0	Double Read
					VISIT 6	24AUG2016	16:38	0	Double Read
					VISIT 7	22FEB2017	16:04	0	Double Read
					VISIT 8	07MAR2018	16:40	0	Double Read
					VISIT 11	10MAR2021	16:14	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	02MAR2016	16:28	N	Double Read
					VISIT 4	21APR2016	16:43	N	Double Read
					VISIT 6	24AUG2016	16:38	N	Double Read
					VISIT 7	22FEB2017	16:04	N	Double Read
					VISIT 8	07MAR2018	16:40	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0152 Age=55 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 11	10MAR2021	16:14	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	16:28	N	Double Read
					VISIT 4	21APR2016	16:43	N	Double Read
					VISIT 6	24AUG2016	16:38	N	Double Read
					VISIT 7	22FEB2017	16:04	N	Double Read
					VISIT 8	07MAR2018	16:40	N	Double Read
					VISIT 11	10MAR2021	16:14	N	Double Read
Relevant scoliosis	5_S		General		Baseline	02MAR2016	16:28	N	Double Read
					VISIT 4	21APR2016	16:43	N	Double Read
					VISIT 6	24AUG2016	16:38	N	Double Read
					VISIT 7	22FEB2017	16:04	N	Double Read
					VISIT 8	07MAR2018	16:40	N	Double Read
					VISIT 11	10MAR2021	16:14	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	02MAR2016	16:28	N	Double Read
					VISIT 4	21APR2016	16:43	N	Double Read
					VISIT 6	24AUG2016	16:38	N	Double Read
					VISIT 7	22FEB2017	16:04	N	Double Read
					VISIT 8	07MAR2018	16:40	N	Double Read
					VISIT 11	10MAR2021	16:14	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	16:28	N	Double Read
					VISIT 4	21APR2016	16:43	N	Double Read
					VISIT 6	24AUG2016	16:38	N	Double Read
					VISIT 7	22FEB2017	16:04	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0152 Age=55 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	07MAR2018	16:40	N	Double Read
					VISIT 11	10MAR2021	16:14	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	02MAR2016	16:28	66.908	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0152 Age=55 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 4	21APR2016	16:43	71.8392	Double Read
					VISIT 6	24AUG2016	16:38	77.3144	Double Read
					VISIT 7	22FEB2017	16:04	71.13952	Double Read
					VISIT 8	07MAR2018	16:40	65.81648	Double Read
					VISIT 11	10MAR2021	16:14	67.66896	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	02MAR2016	16:28	77.9336	Double Read
					VISIT 4	21APR2016	16:43	77.16576	Double Read
					VISIT 6	24AUG2016	16:38	76.83248	Double Read
					VISIT 7	22FEB2017	16:04	76.8104	Double Read
					VISIT 8	07MAR2018	16:40	78.91024	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	10MAR2021	16:14	75.50432	Double Read
					Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0152 Age=55 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0152 Age=55 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	02MAR2016	16:28	lower	Double Read
					VISIT 4	21APR2016	16:43	lower	Double Read
					VISIT 6	24AUG2016	16:38	lower	Double Read
					VISIT 7	22FEB2017	16:04	lower	Double Read
					VISIT 8	07MAR2018	16:40	lower	Double Read
					VISIT 11	10MAR2021	16:14	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0152 Age=55 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0152 Age=55 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	02MAR2016	16:28	9.81447256667	Double Read
					VISIT 4	21APR2016	16:43	10.3193477153	Double Read
					VISIT 6	24AUG2016	16:38	14.2819092916	Double Read
					VISIT 7	22FEB2017	16:04	9.58317649057	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0152 Age=55 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	07MAR2018	16:40	7.3298997791	Double Read
					VISIT 11	10MAR2021	16:14	7.0866383556	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	02MAR2016	16:28	6.0356310514	Double Read
					VISIT 4	21APR2016	16:43	10.783645320	Double Read
					VISIT 6	24AUG2016	16:38	18.907694921	Double Read
					VISIT 7	22FEB2017	16:04	7.0494309495	Double Read
					VISIT 8	07MAR2018	16:40	6.7521657890	Double Read
					VISIT 11	10MAR2021	16:14	15.333242738	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0152 Age=55 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	02MAR2016	16:28	12721.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0152 Age=55 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 4	21APR2016	16:43	11680.5	Double Read
					VISIT 6	24AUG2016	16:38	12247.0	Double Read
					VISIT 7	22FEB2017	16:04	11467.0	Double Read
					VISIT 8	07MAR2018	16:40	11705.5	Double Read
					VISIT 11	10MAR2021	16:14	12508.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	02MAR2016	16:28	15879.5	Double Read
					VISIT 4	21APR2016	16:43	15402.0	Double Read
					VISIT 6	24AUG2016	16:38	15930.5	Double Read
					VISIT 7	22FEB2017	16:04	15340.0	Double Read
					VISIT 8	07MAR2018	16:40	15356.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	02MAR2016	16:28		Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14	17222.0	Double Read
					VISIT 4	21APR2016	16:43		Double Read
					VISIT 6	24AUG2016	16:38		Double Read
					VISIT 7	22FEB2017	16:04		Double Read
					VISIT 8	07MAR2018	16:40		Double Read
					VISIT 11	10MAR2021	16:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S	4_5	Central Disc		Baseline	18MAR2016	15:48	3	Double Read
					VISIT 3A	06JUN2016	16:03	3	Double Read
					VISIT 4	20JUL2016	16:34	3	Double Read
					VISIT 6	30NOV2016	16:48	3	Double Read
					VISIT 7	31MAY2017	16:16	3	Double Read
					VISIT 8	-	16:02	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	18MAR2016	15:48	3	Double Read
					VISIT 3A	06JUN2016	16:03	3	Double Read
					VISIT 4	20JUL2016	16:34	3	Double Read
					VISIT 6	30NOV2016	16:48	3	Double Read
					VISIT 7	31MAY2017	16:16	3	Double Read
					VISIT 8	-	16:02	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S	4_5	Central Disc		Baseline	18MAR2016	15:48	N	Double Read
					VISIT 3A	06JUN2016	16:03	N	Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48	N	Double Read
					VISIT 7	31MAY2017	16:16	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S	4_5	Central Disc		VISIT 8	-	16:02	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	18MAR2016	15:48	N	Double Read
					VISIT 3A	06JUN2016	16:03	N	Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48	N	Double Read
					VISIT 7	31MAY2017	16:16	N	Double Read
					VISIT 8	-	16:02	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
Dorsal disc extrusion (Central Disc)	5_S	4_5	Central Disc		Baseline	18MAR2016	15:48	Y	Double Read
					VISIT 3A	06JUN2016	16:03	Y	Double Read
					VISIT 4	20JUL2016	16:34	Y	Double Read
					VISIT 6	30NOV2016	16:48	Y	Double Read
					VISIT 7	31MAY2017	16:16	Y	Double Read
					VISIT 8	-	16:02	Y	Double Read
Dorsal disc extrusion (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	18MAR2016	15:48	N	Double Read
					VISIT 3A	06JUN2016	16:03	N	Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48	Y	Double Read
					VISIT 7	31MAY2017	16:16	N	Double Read
					VISIT 8	-	16:02	N	Double Read
Extradiscal fluid collection	5_S	4_5	General		Baseline	18MAR2016	15:48	N	Double Read
					VISIT 3A	06JUN2016	16:03	N	Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48	N	Double Read
					VISIT 7	31MAY2017	16:16	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S	4_5	General		VISIT 8	-	16:02	N	Double Read
Fracture	5_S	4_5	General		Baseline	18MAR2016	15:48	N	Double Read
					VISIT 3A	06JUN2016	16:03	N	Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48	N	Double Read
					VISIT 7	31MAY2017	16:16	N	Double Read
					VISIT 8	-	16:02	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	18MAR2016	15:48	12.8	Double Read
					VISIT 3A	06JUN2016	16:03	10.57	Double Read
					VISIT 4	20JUL2016	16:34	11.8	Double Read
					VISIT 6	30NOV2016	16:48	11.385	Double Read
					VISIT 7	31MAY2017	16:16	11.08	Double Read
					VISIT 8	-	16:02	10.125	Double Read
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	18MAR2016	15:48	13.65	Double Read
					VISIT 3A	06JUN2016	16:03	13.465	Double Read
					VISIT 4	20JUL2016	16:34	13.785	Double Read
					VISIT 6	30NOV2016	16:48	13.22	Double Read
					VISIT 7	31MAY2017	16:16	14.185	Double Read
					VISIT 8	-	16:02	14.295	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	18MAR2016	15:48	8.394605	Double Read
					VISIT 3A	06JUN2016	16:03	7.25133	Double Read
					VISIT 4	20JUL2016	16:34	7.31466	Double Read
					VISIT 6	30NOV2016	16:48	8.465405	Double Read
					VISIT 7	31MAY2017	16:16	8.31656	Double Read
					VISIT 8	-	16:02	6.988845	Double Read
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	18MAR2016	15:48	10.525995	Double Read
					VISIT 3A	06JUN2016	16:03	10.074975	Double Read
					VISIT 4	20JUL2016	16:34	10.19025	Double Read
					VISIT 6	30NOV2016	16:48	11.5794	Double Read
					VISIT 7	31MAY2017	16:16	11.51685	Double Read
					VISIT 8	-	16:02	10.8404	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S	4_5	Central Disc		Baseline	18MAR2016	15:48	N	Double Read
					VISIT 3A	06JUN2016	16:03	N	Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48	N	Double Read
					VISIT 7	31MAY2017	16:16	N	Double Read
					VISIT 8	-	16:02	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	18MAR2016	15:48	N	Double Read
					VISIT 3A	06JUN2016	16:03	N	Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48	N	Double Read
					VISIT 7	31MAY2017	16:16	N	Double Read
					VISIT 8	-	16:02	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S	4_5	Central Disc		Baseline	18MAR2016	15:48	N	Double Read
					VISIT 3A	06JUN2016	16:03	N	Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48	N	Double Read
					VISIT 7	31MAY2017	16:16	N	Double Read
					VISIT 8	-	16:02	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	18MAR2016	15:48	N	Double Read
					VISIT 3A	06JUN2016	16:03	N	Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48	N	Double Read
					VISIT 7	31MAY2017	16:16	N	Double Read
					VISIT 8	-	16:02	N	Double Read
Normal lordotic LS	5_S	4_5	General		Baseline	18MAR2016	15:48	Y	Double Read
					VISIT 3A	06JUN2016	16:03	Y	Double Read
					VISIT 4	20JUL2016	16:34	Y	Double Read
					VISIT 6	30NOV2016	16:48	Y	Double Read
					VISIT 7	31MAY2017	16:16	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	5_S	4_5	General		VISIT 8	-	16:02	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S	4_5	Central Disc		Baseline	18MAR2016	15:48	2	Double Read
					VISIT 3A	06JUN2016	16:03	2	Double Read
					VISIT 4	20JUL2016	16:34	0	Double Read
					VISIT 6	30NOV2016	16:48	1	Double Read
					VISIT 7	31MAY2017	16:16	1	Double Read
					VISIT 8	-	16:02	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	18MAR2016	15:48	0	Double Read
					VISIT 3A	06JUN2016	16:03	0	Double Read
					VISIT 4	20JUL2016	16:34	0	Double Read
					VISIT 6	30NOV2016	16:48	0	Double Read
					VISIT 7	31MAY2017	16:16	0	Double Read
					VISIT 8	-	16:02	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
Protruding osteophyte (Central Disc)	5_S	4_5	Central Disc		Baseline	18MAR2016	15:48	N	Double Read
					VISIT 3A	06JUN2016	16:03	N	Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48	N	Double Read
					VISIT 7	31MAY2017	16:16	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S	4_5	Central Disc		VISIT 8	-	16:02	N	Double Read
Protruding osteophyte (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	18MAR2016	15:48	N	Double Read
					VISIT 3A	06JUN2016	16:03	N	Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48	N	Double Read
					VISIT 7	31MAY2017	16:16	N	Double Read
					VISIT 8	-	16:02	N	Double Read
Relevant scoliosis	5_S	4_5	General		Baseline	18MAR2016	15:48	N	Double Read
					VISIT 3A	06JUN2016	16:03	N	Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48	N	Double Read
					VISIT 7	31MAY2017	16:16	N	Double Read
					VISIT 8	-	16:02	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S	4_5	Central Disc		Baseline	18MAR2016	15:48	N	Double Read
					VISIT 3A	06JUN2016	16:03	N	Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48	N	Double Read
					VISIT 7	31MAY2017	16:16	N	Double Read
					VISIT 8	-	16:02	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	18MAR2016	15:48	N	Double Read
					VISIT 3A	06JUN2016	16:03	N	Double Read
					VISIT 4	20JUL2016	16:34	N	Double Read
					VISIT 6	30NOV2016	16:48	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 7	31MAY2017	16:16	N	Double Read
					VISIT 8	-	16:02	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	18MAR2016	15:48	72.43136	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	VISIT 3A	06JUN2016	16:03	72.5552	Double Read
					VISIT 4	20JUL2016	16:34	75.70128	Double Read
					VISIT 6	30NOV2016	16:48	76.49984	Double Read
					VISIT 7	31MAY2017	16:16	73.02208	Double Read
					VISIT 8	-	16:02	78.37408	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
T2 (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
T2 (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	18MAR2016	15:48	75.27008	Double Read
					VISIT 3A	06JUN2016	16:03	72.85216	Double Read
					VISIT 4	20JUL2016	16:34	75.8648	Double Read
					VISIT 6	30NOV2016	16:48	73.4784	Double Read
					VISIT 7	31MAY2017	16:16	76.48656	Double Read
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02	71.1528	Double Read
					VISIT 8	-	16:02		Double Read
					VISIT 8	-	16:02		Double Read
					VISIT 8	-	16:02		Double Read
					VISIT 8	-	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S	4_5	Central Disc		Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	18MAR2016	15:48	equal	Double Read
					VISIT 3A	06JUN2016	16:03	lower	Double Read
					VISIT 4	20JUL2016	16:34	equal	Double Read
					VISIT 6	30NOV2016	16:48	equal	Double Read
					VISIT 7	31MAY2017	16:16	higher	Double Read
					VISIT 8	-	16:02	equal	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	18MAR2016	15:48	equal	Double Read
					VISIT 3A	06JUN2016	16:03	lower	Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48	equal	Double Read
					VISIT 7	31MAY2017	16:16	equal	Double Read
					VISIT 8	-	16:02	equal	Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S	4_5	Central Disc		Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	18MAR2016	15:48	6.4710786478	Double Read
					VISIT 3A	06JUN2016	16:03	6.1021029386	Double Read
					VISIT 4	20JUL2016	16:34	7.4061491421	Double Read
					VISIT 6	30NOV2016	16:48	6.9305248853	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	VISIT 7	31MAY2017	16:16	11.1771700357	Double Read
					VISIT 8	-	16:02	13.0456939019	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	18MAR2016	15:48	7.20716154238	Double Read
					VISIT 3A	06JUN2016	16:03	5.34841515203	Double Read
					VISIT 4	20JUL2016	16:34	11.2111431969	Double Read
					VISIT 6	30NOV2016	16:48	4.73835909631	Double Read
					VISIT 7	31MAY2017	16:16	10.2679599116	Double Read
					VISIT 8	-	16:02	4.77848819432	Double Read
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	18MAR2016	15:48	10331.0	Double Read
					VISIT 3A	06JUN2016	16:03	9017.5	Double Read
					VISIT 4	20JUL2016	16:34	9093.5	Double Read
					VISIT 6	30NOV2016	16:48	8657.5	Double Read
					VISIT 7	31MAY2017	16:16	8384.0	Double Read
					VISIT 8	-	16:02	7349.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read
					VISIT 8	-	16:02		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	18MAR2016	15:48	13148.5	Double Read
					VISIT 3A	06JUN2016	16:03	12847.0	Double Read
					VISIT 4	20JUL2016	16:34	13087.0	Double Read
					VISIT 6	30NOV2016	16:48	12466.5	Double Read
					VISIT 7	31MAY2017	16:16	13382.0	Double Read
					VISIT 8	-	16:02	11945.5	Double Read
Volume (mm^3) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	18MAR2016	15:48		Double Read
					VISIT 3A	06JUN2016	16:03		Double Read
					VISIT 4	20JUL2016	16:34		Double Read
					VISIT 6	30NOV2016	16:48		Double Read
					VISIT 7	31MAY2017	16:16		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=01/0153 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	VISIT 8	-	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5	5_S	Caudal Disc		Baseline	12FEB2013	14:54	3	Double Read
					VISIT 3A	30APR2013	12:05	3	Double Read
					VISIT 3K	08MAY2013	17:06	4	Single Read
					VISIT 3L	28MAY2013	13:41	4	Single Read
					VISIT 4	20JUN2013	8:32	3	Double Read
					VISIT 5	31JUL2013	9:20	3	Double Read
					VISIT 6	29OCT2013	10:37	3	Double Read
					VISIT 7	06MAY2014	11:51	3	Double Read
					VISIT 8	02JUN2015	10:09	3	Double Read
					VISIT 11	29MAY2018	13:30	3	Double Read
					UNSCHEDULED	28DEC2015	13:22	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5	5_S	Central Disc		Baseline	12FEB2013	14:54	3	Double Read
					VISIT 3A	30APR2013	12:05	3	Double Read
					VISIT 3K	08MAY2013	17:06	4	Single Read
					VISIT 3L	28MAY2013	13:41	4	Single Read
					VISIT 4	20JUN2013	8:32	3	Double Read
					VISIT 5	31JUL2013	9:20	3	Double Read
					VISIT 6	29OCT2013	10:37	3	Double Read
					VISIT 7	06MAY2014	11:51	4	Double Read
					VISIT 8	02JUN2015	10:09	4	Double Read
					VISIT 11	29MAY2018	13:30	3	Double Read
					UNSCHEDULED	28DEC2015	13:22	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	4_5	5_S	Cranial Disc, add. treated		Baseline	12FEB2013	14:54	2	Double Read
					VISIT 3A	30APR2013	12:05	2	Double Read
					VISIT 3K	08MAY2013	17:06	3	Single Read
					VISIT 3L	28MAY2013	13:41	3	Single Read
					VISIT 4	20JUN2013	8:32	2	Double Read
					VISIT 5	31JUL2013	9:20	2	Double Read
					VISIT 6	29OCT2013	10:37	2	Double Read
					VISIT 7	06MAY2014	11:51	2	Double Read
					VISIT 8	02JUN2015	10:09	2	Double Read
					VISIT 11	29MAY2018	13:30	2	Double Read
					UNSCHEDULED	28DEC2015	13:22	2	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5	5_S	Caudal Disc		Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5	5_S	Central Disc		UNSCHEDULED	28DEC2015	13:22	N	Double Read
					Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	4_5	5_S	Cranial Disc, add. treated		VISIT 11	29MAY2018	13:30	N	Double Read
					UNSCHEDULED	28DEC2015	13:22	N	Double Read
					Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
					UNSCHEDULED	28DEC2015	13:22	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Caudal Disc)	4_5	5_S	Caudal Disc		Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	Y	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
					UNSCHEDULED	28DEC2015	13:22	Y	Double Read
Dorsal disc extrusion (Central Disc)	4_5	5_S	Central Disc		Baseline	12FEB2013	14:54	Y	Double Read
					VISIT 3A	30APR2013	12:05	Y	Double Read
					VISIT 3K	08MAY2013	17:06	Y	Single Read
					VISIT 3L	28MAY2013	13:41	Y	Single Read
					VISIT 4	20JUN2013	8:32	Y	Double Read
					VISIT 5	31JUL2013	9:20	Y	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	Y	Double Read
					VISIT 8	02JUN2015	10:09	Y	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
					UNSCHEDULED	28DEC2015	13:22	Y	Double Read
Dorsal disc extrusion (Cranial Disc, add. treated)	4_5	5_S	Cranial Disc, add. treated		Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
					UNSCHEDULED	28DEC2015	13:22	N	Double Read
Extradiscal fluid collection	4_5	5_S	General		Baseline	12FEB2013	14:54	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	4_5	5_S	General		VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
Fracture	4_5	5_S	General		UNSCHEDULED	28DEC2015	13:22	N	Double Read
					Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5	5_S	Caudal Disc	Complete Disc	VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
					UNSCHEDULED	28DEC2015	13:22	N	Double Read
					Baseline	12FEB2013	14:54	11.05	Double Read
					VISIT 3A	30APR2013	12:05	12.335	Double Read
					VISIT 3K	08MAY2013	17:06	12.03	Single Read
					VISIT 3L	28MAY2013	13:41	10.03	Single Read
					VISIT 4	20JUN2013	8:32	12.005	Double Read
					VISIT 5	31JUL2013	9:20	12.135	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5	5_S	Central Disc	Complete Disc	VISIT 6	29OCT2013	10:37	11.555	Double Read
					VISIT 7	06MAY2014	11:51	11.72	Double Read
					VISIT 8	02JUN2015	10:09	10.895	Double Read
					VISIT 11	29MAY2018	13:30	10.225	Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
					Baseline	12FEB2013	14:54	13.25	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Central Disc, Complete Disc)	4_5	5_S	Central Disc	Complete Disc	VISIT 3A	30APR2013	12:05	11.81	Double Read
					VISIT 3K	08MAY2013	17:06	12.03	Single Read
					VISIT 3L	28MAY2013	13:41	10.61	Single Read
					VISIT 4	20JUN2013	8:32	12.07	Double Read
					VISIT 5	31JUL2013	9:20	13.17	Double Read
					VISIT 6	29OCT2013	10:37	11.65	Double Read
					VISIT 7	06MAY2014	11:51	10.575	Double Read
					VISIT 8	02JUN2015	10:09	10.64	Double Read
					VISIT 11	29MAY2018	13:30	8.32	Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	4_5	5_S	Cranial Disc, add. treated	Complete Disc	Baseline	12FEB2013	14:54	14.625	Double Read
					VISIT 3A	30APR2013	12:05	15.715	Double Read
					VISIT 3K	08MAY2013	17:06	12.03	Single Read
					VISIT 3L	28MAY2013	13:41	12.53	Single Read
					VISIT 4	20JUN2013	8:32	14.89	Double Read
					VISIT 5	31JUL2013	9:20	15.475	Double Read
					VISIT 6	29OCT2013	10:37	15.97	Double Read
					VISIT 7	06MAY2014	11:51	13.335	Double Read
					VISIT 8	02JUN2015	10:09	14.075	Double Read
					VISIT 11	29MAY2018	13:30	14.03	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5	5_S	Caudal Disc	Complete Disc	Baseline	12FEB2013	14:54	8.1209	Double Read
					VISIT 3A	30APR2013	12:05	8.404165	Double Read
					VISIT 3K	08MAY2013	17:06	7.62571	Single Read
					VISIT 3L	28MAY2013	13:41	8.60936	Single Read
					VISIT 4	20JUN2013	8:32	7.477685	Double Read
					VISIT 5	31JUL2013	9:20	8.29732	Double Read
					VISIT 6	29OCT2013	10:37	8.3905	Double Read
					VISIT 7	06MAY2014	11:51	8.23399	Double Read
					VISIT 8	02JUN2015	10:09	7.64508	Double Read
					VISIT 11	29MAY2018	13:30	7.940395	Double Read
					UNSCHEDULED	28DEC2015	13:22	7.99229	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Central Disc, Complete Disc)	4_5	5_S	Central Disc	Complete Disc	Baseline	12FEB2013	14:54	9.372755	Double Read
					VISIT 3A	30APR2013	12:05	8.986875	Double Read
					VISIT 3K	08MAY2013	17:06	8.79508	Single Read
					VISIT 3L	28MAY2013	13:41	11.3913	Single Read
					VISIT 4	20JUN2013	8:32	9.345565	Double Read
					VISIT 5	31JUL2013	9:20	9.126955	Double Read
					VISIT 6	29OCT2013	10:37	9.28089	Double Read
					VISIT 7	06MAY2014	11:51	9.26861	Double Read
					VISIT 8	02JUN2015	10:09	9.406715	Double Read
					VISIT 11	29MAY2018	13:30	7.222755	Double Read
					UNSCHEDULED	28DEC2015	13:22	8.433955	Double Read
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	4_5	5_S	Cranial Disc, add. treated	Complete Disc	Baseline	12FEB2013	14:54	11.40505	Double Read
					VISIT 3A	30APR2013	12:05	11.83185	Double Read
					VISIT 3K	08MAY2013	17:06	11.2353	Single Read
					VISIT 3L	28MAY2013	13:41	10.8113	Single Read
					VISIT 4	20JUN2013	8:32	11.67535	Double Read
					VISIT 5	31JUL2013	9:20	12.59705	Double Read
					VISIT 6	29OCT2013	10:37	11.76285	Double Read
					VISIT 7	06MAY2014	11:51	11.6437	Double Read
					VISIT 8	02JUN2015	10:09	11.7238	Double Read
					VISIT 11	29MAY2018	13:30	12.1087	Double Read
					UNSCHEDULED	28DEC2015	13:22	12.1651	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5	5_S	Caudal Disc		Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5	5_S	Caudal Disc		UNSCHEDULED	28DEC2015	13:22	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5	5_S	Central Disc		Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
					UNSCHEDULED	28DEC2015	13:22	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, add. treated)	4_5	5_S	Cranial Disc, add. treated		Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
					UNSCHEDULED	28DEC2015	13:22	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5	5_S	Caudal Disc		Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5	5_S	Caudal Disc		VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
					UNSCHEDULED	28DEC2015	13:22	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5	5_S	Central Disc		Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
					UNSCHEDULED	28DEC2015	13:22	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, add. treated)	4_5	5_S	Cranial Disc, add. treated		Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
					UNSCHEDULED	28DEC2015	13:22	N	Double Read
Normal lordotic LS	4_5	5_S	General		Baseline	12FEB2013	14:54	Y	Double Read
					VISIT 3A	30APR2013	12:05	Y	Double Read
					VISIT 3K	08MAY2013	17:06	Y	Single Read
					VISIT 3L	28MAY2013	13:41	Y	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	4_5	5_S	General		VISIT 4	20JUN2013	8:32	Y	Double Read
					VISIT 5	31JUL2013	9:20	Y	Double Read
					VISIT 6	29OCT2013	10:37	Y	Double Read
					VISIT 7	06MAY2014	11:51	Y	Double Read
					VISIT 8	02JUN2015	10:09	Y	Double Read
					VISIT 11	29MAY2018	13:30	Y	Double Read
					UNSCHEDULED	28DEC2015	13:22	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5	5_S	Caudal Disc		Baseline	12FEB2013	14:54	0	Double Read
					VISIT 3A	30APR2013	12:05	0	Double Read
					VISIT 3K	08MAY2013	17:06	0	Single Read
					VISIT 3L	28MAY2013	13:41	0	Single Read
					VISIT 4	20JUN2013	8:32	0	Double Read
					VISIT 5	31JUL2013	9:20	0	Double Read
					VISIT 6	29OCT2013	10:37	0	Double Read
					VISIT 7	06MAY2014	11:51	0	Double Read
					VISIT 8	02JUN2015	10:09	0	Double Read
					VISIT 11	29MAY2018	13:30	0	Double Read
					UNSCHEDULED	28DEC2015	13:22	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5	5_S	Central Disc		Baseline	12FEB2013	14:54	2	Double Read
					VISIT 3A	30APR2013	12:05	2	Double Read
					VISIT 3K	08MAY2013	17:06	2	Single Read
					VISIT 3L	28MAY2013	13:41	2	Single Read
					VISIT 4	20JUN2013	8:32	2	Double Read
					VISIT 5	31JUL2013	9:20	0	Double Read
					VISIT 6	29OCT2013	10:37	0	Double Read
					VISIT 7	06MAY2014	11:51	1	Double Read
					VISIT 8	02JUN2015	10:09	2	Double Read
					VISIT 11	29MAY2018	13:30	2	Double Read
					UNSCHEDULED	28DEC2015	13:22	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	4_5	5_S	Cranial Disc, add. treated		Baseline	12FEB2013	14:54	0	Double Read
					VISIT 3A	30APR2013	12:05	0	Double Read
					VISIT 3K	08MAY2013	17:06	0	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	4_5	5_S	Cranial Disc, add. treated		VISIT 3L	28MAY2013	13:41	0	Single Read
					VISIT 4	20JUN2013	8:32	0	Double Read
					VISIT 5	31JUL2013	9:20	0	Double Read
					VISIT 6	29OCT2013	10:37	0	Double Read
					VISIT 7	06MAY2014	11:51	0	Double Read
					VISIT 8	02JUN2015	10:09	0	Double Read
					VISIT 11	29MAY2018	13:30	0	Double Read
					UNSCHEDULED	28DEC2015	13:22	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5	5_S	Caudal Disc		Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
					UNSCHEDULED	28DEC2015	13:22	N	Double Read
Protruding osteophyte (Central Disc)	4_5	5_S	Central Disc		Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
					UNSCHEDULED	28DEC2015	13:22	N	Double Read
Protruding osteophyte (Cranial Disc, add. treated)	4_5	5_S	Cranial Disc, add. treated		Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, add. treated)	4_5	5_S	Cranial Disc, add. treated		VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
					UNSCHEDULED	28DEC2015	13:22	N	Double Read
Relevant scoliosis	4_5	5_S	General		Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5	5_S	Caudal Disc		Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5	5_S	Central Disc		Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5	5_S	Central Disc		VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
					UNSCHEDULED	28DEC2015	13:22	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	4_5	5_S	Cranial Disc, add. treated		Baseline	12FEB2013	14:54	N	Double Read
					VISIT 3A	30APR2013	12:05	N	Double Read
					VISIT 3K	08MAY2013	17:06	N	Single Read
					VISIT 3L	28MAY2013	13:41	N	Single Read
					VISIT 4	20JUN2013	8:32	N	Double Read
					VISIT 5	31JUL2013	9:20	N	Double Read
					VISIT 6	29OCT2013	10:37	N	Double Read
					VISIT 7	06MAY2014	11:51	N	Double Read
					VISIT 8	02JUN2015	10:09	N	Double Read
					VISIT 11	29MAY2018	13:30	N	Double Read
					UNSCHEDULED	28DEC2015	13:22	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5	5_S	Caudal Disc	Anulus Fibrosus	Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06		Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Complete Disc)	4_5	5_S	Caudal Disc	Complete Disc	Baseline	12FEB2013	14:54	88.28624	Double Read
					VISIT 3A	30APR2013	12:05	87.23488	Double Read
					VISIT 3K	08MAY2013	17:06	91.05056	Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32	99.9568	Double Read
					VISIT 5	31JUL2013	9:20	83.21632	Double Read
					VISIT 6	29OCT2013	10:37	88.89328	Double Read
					VISIT 7	06MAY2014	11:51	88.61904	Double Read
					VISIT 8	02JUN2015	10:09	64.72112	Double Read
					VISIT 11	29MAY2018	13:30	70.26624	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5	5_S	Caudal Disc	Nucleus Pulposus	UNSCHEDULED	28DEC2015	13:22		Double Read
					Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06		Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5	5_S	Central Disc	Anulus Fibrosus	VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
					Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06		Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
					Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06		Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5	5_S	Central Disc	Complete Disc	Baseline	12FEB2013	14:54	92.71104	Double Read
					VISIT 3A	30APR2013	12:05	78.46672	Double Read
					VISIT 3K	08MAY2013	17:06	92.0144	Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32	97.9464	Double Read
					VISIT 5	31JUL2013	9:20	86.33296	Double Read
					VISIT 6	29OCT2013	10:37	90.40896	Double Read
					VISIT 7	06MAY2014	11:51	82.67296	Double Read
					VISIT 8	02JUN2015	10:09	63.35728	Double Read
					VISIT 11	29MAY2018	13:30	100.56832	Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5	5_S	Central Disc	Nucleus Pulposus	Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06		Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
T2 (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	5_S	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06	116.87328	Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, add. treated, Complete Disc)	4_5	5_S	Cranial Disc, add. treated	Complete Disc	Baseline	12FEB2013	14:54	112.25888	Double Read
					VISIT 3A	30APR2013	12:05	100.38528	Double Read
					VISIT 3K	08MAY2013	17:06	113.23648	Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32	112.16576	Double Read
					VISIT 5	31JUL2013	9:20	104.77344	Double Read
					VISIT 6	29OCT2013	10:37	107.16256	Double Read
					VISIT 7	06MAY2014	11:51	106.43024	Double Read
					VISIT 8	02JUN2015	10:09	84.12176	Double Read
					VISIT 11	29MAY2018	13:30	87.89872	Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	5_S	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06	114.03104	Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5	5_S	Caudal Disc		Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06	higher	Single Read
					VISIT 3L	28MAY2013	13:41	equal	Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5	5_S	Caudal Disc		UNSCHEDULED	28DEC2015	13:22		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5	5_S	Central Disc		Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06	equal	Single Read
					VISIT 3L	28MAY2013	13:41	equal	Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	4_5	5_S	Cranial Disc, add. treated		Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06	equal	Single Read
					VISIT 3L	28MAY2013	13:41	equal	Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5	5_S	Caudal Disc		Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06		Single Read
					VISIT 3L	28MAY2013	13:41		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5	5_S	Caudal Disc		VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5	5_S	Central Disc		Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05	equal	Double Read
					VISIT 3K	08MAY2013	17:06	lower	Single Read
					VISIT 3L	28MAY2013	13:41	equal	Single Read
					VISIT 4	20JUN2013	8:32	equal	Double Read
					VISIT 5	31JUL2013	9:20	equal	Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09	lower	Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, add. treated,)	4_5	5_S	Cranial Disc, add. treated		Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06		Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5	5_S	Caudal Disc		Baseline	12FEB2013	14:54	lower	Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06	higher	Single Read
					VISIT 3L	28MAY2013	13:41	equal	Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51	lower	Double Read
					VISIT 8	02JUN2015	10:09	lower	Double Read
					VISIT 11	29MAY2018	13:30	lower	Double Read
					UNSCHEDULED	28DEC2015	13:22	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5	5_S	Central Disc		Baseline	12FEB2013	14:54	lower	Double Read
					VISIT 3A	30APR2013	12:05	lower	Double Read
					VISIT 3K	08MAY2013	17:06	lower	Single Read
					VISIT 3L	28MAY2013	13:41	lower	Single Read
					VISIT 4	20JUN2013	8:32	lower	Double Read
					VISIT 5	31JUL2013	9:20	lower	Double Read
					VISIT 6	29OCT2013	10:37	lower	Double Read
					VISIT 7	06MAY2014	11:51	lower	Double Read
					VISIT 8	02JUN2015	10:09	lower	Double Read
					VISIT 11	29MAY2018	13:30	lower	Double Read
					UNSCHEDULED	28DEC2015	13:22	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, add. treated,)	4_5	5_S	Cranial Disc, add. treated		Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06		Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, add. treated,)	4_5	5_S	Cranial Disc, add. treated		VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5	5_S	Caudal Disc		Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06	higher	Single Read
					VISIT 3L	28MAY2013	13:41	equal	Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5	5_S	Central Disc		Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06	equal	Single Read
					VISIT 3L	28MAY2013	13:41	equal	Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, add. treated,)	4_5	5_S	Cranial Disc, add. treated		Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06	equal	Single Read
					VISIT 3L	28MAY2013	13:41	equal	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Cranial Disc, add. treated,)	4_5	5_S	Cranial Disc, add. treated		VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5	5_S	Caudal Disc	Anulus Fibrosus	Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06		Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5	5_S	Caudal Disc	Complete Disc	Baseline	12FEB2013	14:54	13.0097231187	Double Read
					VISIT 3A	30APR2013	12:05	15.5575335485	Double Read
					VISIT 3K	08MAY2013	17:06	11.9041956854	Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32	13.3769322235	Double Read
					VISIT 5	31JUL2013	9:20	15.0797350093	Double Read
					VISIT 6	29OCT2013	10:37	16.0693052489	Double Read
					VISIT 7	06MAY2014	11:51	15.0208255478	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Complete Disc)	4_5	5_S	Caudal Disc	Complete Disc	VISIT 8	02JUN2015	10:09	4.79870901987	Double Read
					VISIT 11	29MAY2018	13:30	9.34107694923	Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5	5_S	Caudal Disc	Nucleus Pulposus	Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06		Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5	5_S	Central Disc	Anulus Fibrosus	Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06		Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5	5_S	Central Disc	Complete Disc	Baseline	12FEB2013	14:54	11.2078953627	Double Read
					VISIT 3A	30APR2013	12:05	14.7975539324	Double Read
					VISIT 3K	08MAY2013	17:06	11.1658501784	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	4_5	5_S	Central Disc	Complete Disc	VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32	14.249838627	Double Read
					VISIT 5	31JUL2013	9:20	15.454187192	Double Read
					VISIT 6	29OCT2013	10:37	16.100540173	Double Read
					VISIT 7	06MAY2014	11:51	12.583686087	Double Read
					VISIT 8	02JUN2015	10:09	2.3966502463	Double Read
					VISIT 11 UNSCHEDULED	29MAY2018 28DEC2015	13:30 13:22	2.5363954476	Double Read Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5	5_S	Central Disc	Nucleus Pulposus	Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06		Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	5_S	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06	25.480278579	Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	5_S	Cranial Disc, add. treated	Anulus Fibrosus	VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	4_5	5_S	Cranial Disc, add. treated	Complete Disc	Baseline	12FEB2013	14:54	11.3198097503	Double Read
					VISIT 3A	30APR2013	12:05	20.3676575505	Double Read
					VISIT 3K	08MAY2013	17:06	16.2159334126	Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32	14.9028707321	Double Read
					VISIT 5	31JUL2013	9:20	21.5921861729	Double Read
					VISIT 6	29OCT2013	10:37	16.3114659419	Double Read
					VISIT 7	06MAY2014	11:51	16.9796500764	Double Read
					VISIT 8	02JUN2015	10:09	8.77640224225	Double Read
					VISIT 11	29MAY2018	13:30	2.25072192967	Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	5_S	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06	16.6707660948	Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	5_S	Cranial Disc, add. treated	Nucleus Pulposus	UNSCHEDULED	28DEC2015	13:22		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5	5_S	Caudal Disc	Anulus Fibrosus	Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06		Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5	5_S	Caudal Disc	Complete Disc	Baseline	12FEB2013	14:54	9951.0	Double Read
					VISIT 3A	30APR2013	12:05	10242.5	Double Read
					VISIT 3K	08MAY2013	17:06	8727	Single Read
					VISIT 3L	28MAY2013	13:41	8058	Single Read
					VISIT 4	20JUN2013	8:32	10036.5	Double Read
					VISIT 5	31JUL2013	9:20	10830.5	Double Read
					VISIT 6	29OCT2013	10:37	10131.0	Double Read
					VISIT 7	06MAY2014	11:51	10659.0	Double Read
					VISIT 8	02JUN2015	10:09	9222.5	Double Read
					VISIT 11	29MAY2018	13:30	8409.5	Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5	5_S	Caudal Disc	Nucleus Pulposus	Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06		Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5	5_S	Caudal Disc	Nucleus Pulposus	VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5	5_S	Central Disc	Anulus Fibrosus	Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06		Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5	5_S	Central Disc	Complete Disc	Baseline	12FEB2013	14:54	13733.0	Double Read
					VISIT 3A	30APR2013	12:05	12635.5	Double Read
					VISIT 3K	08MAY2013	17:06	8727	Single Read
					VISIT 3L	28MAY2013	13:41	10723	Single Read
					VISIT 4	20JUN2013	8:32	12626.5	Double Read
					VISIT 5	31JUL2013	9:20	12791.0	Double Read
					VISIT 6	29OCT2013	10:37	12624.0	Double Read
					VISIT 7	06MAY2014	11:51	12861.0	Double Read
					VISIT 8	02JUN2015	10:09	11041.0	Double Read
					VISIT 11	29MAY2018	13:30	7800.0	Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5	5_S	Central Disc	Nucleus Pulposus	Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06		Single Read
					VISIT 3L	28MAY2013	13:41		Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Nucleus Pulposus)	4_5	5_S	Central Disc	Nucleus Pulposus	VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
Volume (mm ³) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	5_S	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06	3503	Single Read
					VISIT 3L	28MAY2013	13:41	7788	Single Read
					VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
Volume (mm ³) (Cranial Disc, add. treated, Complete Disc)	4_5	5_S	Cranial Disc, add. treated	Complete Disc	Baseline	12FEB2013	14:54	15324.0	Double Read
					VISIT 3A	30APR2013	12:05	16012.5	Double Read
					VISIT 3K	08MAY2013	17:06	8727	Single Read
					VISIT 3L	28MAY2013	13:41	12509	Single Read
					VISIT 4	20JUN2013	8:32	15829.5	Double Read
					VISIT 5	31JUL2013	9:20	15583.0	Double Read
					VISIT 6	29OCT2013	10:37	15594.5	Double Read
					VISIT 7	06MAY2014	11:51	14631.5	Double Read
					VISIT 8	02JUN2015	10:09	13914.5	Double Read
					VISIT 11	29MAY2018	13:30	13918.5	Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read
Volume (mm ³) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	5_S	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	12FEB2013	14:54		Double Read
					VISIT 3A	30APR2013	12:05		Double Read
					VISIT 3K	08MAY2013	17:06	5224	Single Read
					VISIT 3L	28MAY2013	13:41	4721	Single Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0201 Age=43 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	5_S	Cranial Disc, add. treated	Nucleus Pulposus	VISIT 4	20JUN2013	8:32		Double Read
					VISIT 5	31JUL2013	9:20		Double Read
					VISIT 6	29OCT2013	10:37		Double Read
					VISIT 7	06MAY2014	11:51		Double Read
					VISIT 8	02JUN2015	10:09		Double Read
					VISIT 11	29MAY2018	13:30		Double Read
					UNSCHEDULED	28DEC2015	13:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0202 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	20MAR2013	8:59		Single Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	20MAR2013	8:59	4	Single Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	20MAR2013	8:59	2	Single Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	20MAR2013	8:59		Single Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	20MAR2013	8:59	N	Single Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	20MAR2013	8:59	N	Single Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	20MAR2013	8:59		Single Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	20MAR2013	8:59	Y	Single Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	20MAR2013	8:59	N	Single Read
Extradiscal fluid collection	5_S		General		Baseline	20MAR2013	8:59	N	Single Read
Fracture	5_S		General		Baseline	20MAR2013	8:59	N	Single Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	20MAR2013	8:59		Single Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	20MAR2013	8:59	12.13	Single Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	20MAR2013	8:59	13.77	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0202 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	20MAR2013	8:59		Single Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	20MAR2013	8:59	10.3472	Single Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	20MAR2013	8:59	13.1502	Single Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	20MAR2013	8:59		Single Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	20MAR2013	8:59	N	Single Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	20MAR2013	8:59	N	Single Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	20MAR2013	8:59		Single Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	20MAR2013	8:59	N	Single Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	20MAR2013	8:59	N	Single Read
Normal lordotic LS	5_S		General		Baseline	20MAR2013	8:59	Y	Single Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	20MAR2013	8:59		Single Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	20MAR2013	8:59	0	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0202 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	20MAR2013	8:59	0	Single Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	20MAR2013	8:59		Single Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	20MAR2013	8:59	N	Single Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	20MAR2013	8:59	N	Single Read
Relevant scoliosis	5_S		General		Baseline	20MAR2013	8:59	N	Single Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	20MAR2013	8:59		Single Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	20MAR2013	8:59	N	Single Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	20MAR2013	8:59	N	Single Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	20MAR2013	8:59		Single Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	20MAR2013	8:59		Single Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	20MAR2013	8:59		Single Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	20MAR2013	8:59		Single Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	20MAR2013	8:59	90.34464	Single Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	20MAR2013	8:59		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0202 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	20MAR2013	8:59	120.2688	Single Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	20MAR2013	8:59	102.50208	Single Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	20MAR2013	8:59	106.54656	Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	20MAR2013	8:59		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	20MAR2013	8:59		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	20MAR2013	8:59		Single Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	20MAR2013	8:59		Single Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	20MAR2013	8:59		Single Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	20MAR2013	8:59		Single Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	20MAR2013	8:59		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0202 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	20MAR2013	8:59	lower	Single Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	20MAR2013	8:59		Single Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	20MAR2013	8:59		Single Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	20MAR2013	8:59		Single Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	20MAR2013	8:59		Single Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	20MAR2013	8:59		Single Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	20MAR2013	8:59		Single Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	20MAR2013	8:59		Single Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	20MAR2013	8:59		Single Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	20MAR2013	8:59	11.946132155 6	Single Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	20MAR2013	8:59		Single Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	20MAR2013	8:59	22.163410905 4	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0202 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	20MAR2013	8:59	15.409274673	Single Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	20MAR2013	8:59	14.3779853915	Single Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	20MAR2013	8:59		Single Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	20MAR2013	8:59		Single Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	20MAR2013	8:59		Single Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	20MAR2013	8:59		Single Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	20MAR2013	8:59	10148	Single Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	20MAR2013	8:59		Single Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	20MAR2013	8:59	6961	Single Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	20MAR2013	8:59	13565	Single Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	20MAR2013	8:59	6604	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	27MAR2013	15:25	3	Double Read
					VISIT 3A	25JUN2013	14:20	3	Double Read
					VISIT 3K	28JUN2013	12:20	3	Single Read
					VISIT 3L	24JUL2013	12:56	3	Single Read
					VISIT 4	13AUG2013	11:04	2	Double Read
					VISIT 5	24SEP2013	10:58	2	Double Read
					VISIT 6	10DEC2013	10:07	2	Double Read
					VISIT 7	26JUN2014	8:56	2	Double Read
					VISIT 8	24JUN2015	14:05	2	Double Read
					VISIT 11	26JUN2018	13:24	3	Double Read
					UNSCHEDULED	05MAR2014	7:55	3	Double Read
					UNSCHEDULED	10FEB2016	8:16	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5	3_4	Central Disc		Baseline	27MAR2013	15:25	3	Double Read
					VISIT 3A	25JUN2013	14:20	3	Double Read
					VISIT 3K	28JUN2013	12:20	4	Single Read
					VISIT 3L	24JUL2013	12:56	4	Single Read
					VISIT 4	13AUG2013	11:04	3	Double Read
					VISIT 5	24SEP2013	10:58	3	Double Read
					VISIT 6	10DEC2013	10:07	3	Double Read
					VISIT 7	26JUN2014	8:56	2	Double Read
					VISIT 8	24JUN2015	14:05	2	Double Read
					VISIT 11	26JUN2018	13:24	3	Double Read
					UNSCHEDULED	05MAR2014	7:55	3	Double Read
					UNSCHEDULED	10FEB2016	8:16	2	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	27MAR2013	15:25	3	Double Read
					VISIT 3A	25JUN2013	14:20	4	Double Read
					VISIT 3K	28JUN2013	12:20	4	Single Read
					VISIT 3L	24JUL2013	12:56	4	Single Read
					VISIT 4	13AUG2013	11:04	3	Double Read
					VISIT 5	24SEP2013	10:58	3	Double Read
					VISIT 6	10DEC2013	10:07	3	Double Read
					VISIT 7	26JUN2014	8:56	3	Double Read
					VISIT 8	24JUN2015	14:05	3	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		VISIT 11	26JUN2018	13:24	2	Double Read
					UNSCHEDULED	05MAR2014	7:55	3	Double Read
					UNSCHEDULED	10FEB2016	8:16	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read
					VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read
					UNSCHEDULED	10FEB2016	8:16	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5	3_4	Central Disc		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read
					VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read
					UNSCHEDULED	10FEB2016	8:16	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read
					UNSCHEDULED	10FEB2016	8:16	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read
					VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read
					UNSCHEDULED	10FEB2016	8:16	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5	3_4	Central Disc		Baseline	27MAR2013	15:25	Y	Double Read
					VISIT 3A	25JUN2013	14:20	Y	Double Read
					VISIT 3K	28JUN2013	12:20	Y	Single Read
					VISIT 3L	24JUL2013	12:56	Y	Single Read
					VISIT 4	13AUG2013	11:04	Y	Double Read
					VISIT 5	24SEP2013	10:58	Y	Double Read
					VISIT 6	10DEC2013	10:07	Y	Double Read
					VISIT 7	26JUN2014	8:56	Y	Double Read
					VISIT 8	24JUN2015	14:05	Y	Double Read
					VISIT 11	26JUN2018	13:24	Y	Double Read
					UNSCHEDULED	05MAR2014	7:55	Y	Double Read
					UNSCHEDULED	10FEB2016	8:16	Y	Double Read
Dorsal disc extrusion (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	27MAR2013	15:25	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read
					VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	Y	Double Read
					UNSCHEDULED	10FEB2016	8:16	N	Double Read
Extradiscal fluid collection	4_5	3_4	General		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read
					VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read
					UNSCHEDULED	10FEB2016	8:16	N	Double Read
Fracture	4_5	3_4	General		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read
					VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read
					UNSCHEDULED	10FEB2016	8:16	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	27MAR2013	15:25	11.89	Double Read
					VISIT 3A	25JUN2013	14:20	10.965	Double Read
					VISIT 3K	28JUN2013	12:20	11.75	Single Read
					VISIT 3L	24JUL2013	12:56	9.92	Single Read
					VISIT 4	13AUG2013	11:04	11.605	Double Read
					VISIT 5	24SEP2013	10:58	12.535	Double Read
					VISIT 6	10DEC2013	10:07	11.33	Double Read
					VISIT 7	26JUN2014	8:56	12.17	Double Read
					VISIT 8	24JUN2015	14:05	11.415	Double Read
					VISIT 11	26JUN2018	13:24	12.445	Double Read
					UNSCHEDULED	05MAR2014	7:55	11.35	Double Read
					UNSCHEDULED	10FEB2016	8:16	12.545	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	27MAR2013	15:25	12.745	Double Read
					VISIT 3A	25JUN2013	14:20	13.96	Double Read
					VISIT 3K	28JUN2013	12:20	12.92	Single Read
					VISIT 3L	24JUL2013	12:56	12.04	Single Read
					VISIT 4	13AUG2013	11:04	12.625	Double Read
					VISIT 5	24SEP2013	10:58	14.85	Double Read
					VISIT 6	10DEC2013	10:07	14.325	Double Read
					VISIT 7	26JUN2014	8:56	12.885	Double Read
					VISIT 8	24JUN2015	14:05	11.915	Double Read
					VISIT 11	26JUN2018	13:24	11.815	Double Read
					UNSCHEDULED	05MAR2014	7:55	13.87	Double Read
					UNSCHEDULED	10FEB2016	8:16	13.42	Double Read
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	27MAR2013	15:25	12.13	Double Read
					VISIT 3A	25JUN2013	14:20	12.22	Double Read
					VISIT 3K	28JUN2013	12:20	10.50	Single Read
					VISIT 3L	24JUL2013	12:56	10.52	Single Read
					VISIT 4	13AUG2013	11:04	10.275	Double Read
					VISIT 5	24SEP2013	10:58	12.86	Double Read
					VISIT 6	10DEC2013	10:07	13.245	Double Read
					VISIT 7	26JUN2014	8:56	10.205	Double Read
					VISIT 8	24JUN2015	14:05	11.93	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	VISIT 11	26JUN2018	13:24	10.8	Double Read
					UNSCHEDULED	05MAR2014	7:55	12.73	Double Read
					UNSCHEDULED	10FEB2016	8:16	12.91	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	27MAR2013	15:25	7.825125	Double Read
					VISIT 3A	25JUN2013	14:20	7.676785	Double Read
					VISIT 3K	28JUN2013	12:20	7.72264	Single Read
					VISIT 3L	24JUL2013	12:56	7.74905	Single Read
					VISIT 4	13AUG2013	11:04	7.33193	Double Read
					VISIT 5	24SEP2013	10:58	7.10984	Double Read
					VISIT 6	10DEC2013	10:07	6.96437	Double Read
					VISIT 7	26JUN2014	8:56	7.48387	Double Read
					VISIT 8	24JUN2015	14:05	6.58496	Double Read
					VISIT 11	26JUN2018	13:24	6.552885	Double Read
					UNSCHEDULED	05MAR2014	7:55	7.625585	Double Read
					UNSCHEDULED	10FEB2016	8:16	6.81652	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	27MAR2013	15:25	10.6014	Double Read
					VISIT 3A	25JUN2013	14:20	10.8989	Double Read
					VISIT 3K	28JUN2013	12:20	11.6133	Single Read
					VISIT 3L	24JUL2013	12:56	10.7918	Single Read
					VISIT 4	13AUG2013	11:04	10.15335	Double Read
					VISIT 5	24SEP2013	10:58	10.41355	Double Read
					VISIT 6	10DEC2013	10:07	10.80845	Double Read
					VISIT 7	26JUN2014	8:56	11.6118	Double Read
					VISIT 8	24JUN2015	14:05	9.81192	Double Read
					VISIT 11	26JUN2018	13:24	8.482955	Double Read
					UNSCHEDULED	05MAR2014	7:55	10.6708	Double Read
					UNSCHEDULED	10FEB2016	8:16	9.638955	Double Read
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	27MAR2013	15:25	8.633595	Double Read
					VISIT 3A	25JUN2013	14:20	8.52521	Double Read
					VISIT 3K	28JUN2013	12:20	9.68474	Single Read
					VISIT 3L	24JUL2013	12:56	8.10152	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	VISIT 4	13AUG2013	11:04	8.90038	Double Read
					VISIT 5	24SEP2013	10:58	8.944325	Double Read
					VISIT 6	10DEC2013	10:07	9.206375	Double Read
					VISIT 7	26JUN2014	8:56	9.308235	Double Read
					VISIT 8	24JUN2015	14:05	8.536895	Double Read
					VISIT 11	26JUN2018	13:24	7.499975	Double Read
					UNSCHEDULED	05MAR2014	7:55	8.62478	Double Read
					UNSCHEDULED	10FEB2016	8:16	7.84322	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read
					VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read
					UNSCHEDULED	10FEB2016	8:16	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5	3_4	Central Disc		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read
					VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5	3_4	Central Disc		UNSCHEDULED	10FEB2016	8:16	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read
					VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read
					UNSCHEDULED	10FEB2016	8:16	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read
					VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read
					UNSCHEDULED	10FEB2016	8:16	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5	3_4	Central Disc		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5	3_4	Central Disc		VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read
					UNSCHEDULED	10FEB2016	8:16	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read
					VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read
					UNSCHEDULED	10FEB2016	8:16	N	Double Read
Normal lordotic LS	4_5	3_4	General		Baseline	27MAR2013	15:25	Y	Double Read
					VISIT 3A	25JUN2013	14:20	Y	Double Read
					VISIT 3K	28JUN2013	12:20	Y	Single Read
					VISIT 3L	24JUL2013	12:56	Y	Single Read
					VISIT 4	13AUG2013	11:04	Y	Double Read
					VISIT 5	24SEP2013	10:58	Y	Double Read
					VISIT 6	10DEC2013	10:07	Y	Double Read
					VISIT 7	26JUN2014	8:56	Y	Double Read
					VISIT 8	24JUN2015	14:05	Y	Double Read
					VISIT 11	26JUN2018	13:24	Y	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read
					UNSCHEDULED	10FEB2016	8:16	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	27MAR2013	15:25	0	Double Read
					VISIT 3A	25JUN2013	14:20	0	Double Read
					VISIT 3K	28JUN2013	12:20	2	Single Read
					VISIT 3L	24JUL2013	12:56	2	Single Read
					VISIT 4	13AUG2013	11:04	0	Double Read
					VISIT 5	24SEP2013	10:58	0	Double Read
					VISIT 6	10DEC2013	10:07	2	Double Read
					VISIT 7	26JUN2014	8:56	0	Double Read
					VISIT 8	24JUN2015	14:05	0	Double Read
					VISIT 11	26JUN2018	13:24	2	Double Read
					UNSCHEDULED	05MAR2014	7:55	0	Double Read
					UNSCHEDULED	10FEB2016	8:16	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5	3_4	Central Disc		Baseline	27MAR2013	15:25	0	Double Read
					VISIT 3A	25JUN2013	14:20	0	Double Read
					VISIT 3K	28JUN2013	12:20	0	Single Read
					VISIT 3L	24JUL2013	12:56	0	Single Read
					VISIT 4	13AUG2013	11:04	0	Double Read
					VISIT 5	24SEP2013	10:58	0	Double Read
					VISIT 6	10DEC2013	10:07	0	Double Read
					VISIT 7	26JUN2014	8:56	0	Double Read
					VISIT 8	24JUN2015	14:05	1	Double Read
					VISIT 11	26JUN2018	13:24	2	Double Read
					UNSCHEDULED	05MAR2014	7:55	0	Double Read
					UNSCHEDULED	10FEB2016	8:16	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	27MAR2013	15:25	0	Double Read
					VISIT 3A	25JUN2013	14:20	0	Double Read
					VISIT 3K	28JUN2013	12:20	0	Single Read
					VISIT 3L	24JUL2013	12:56	0	Single Read
					VISIT 4	13AUG2013	11:04	0	Double Read
					VISIT 5	24SEP2013	10:58	0	Double Read
					VISIT 6	10DEC2013	10:07	0	Double Read
					VISIT 7	26JUN2014	8:56	0	Double Read
					VISIT 8	24JUN2015	14:05	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		VISIT 11	26JUN2018	13:24	0	Double Read
					UNSCHEDULED	05MAR2014	7:55	0	Double Read
					UNSCHEDULED	10FEB2016	8:16	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read
					VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	Y	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read
					UNSCHEDULED	10FEB2016	8:16	N	Double Read
Protruding osteophyte (Central Disc)	4_5	3_4	Central Disc		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read
					VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read
					UNSCHEDULED	10FEB2016	8:16	N	Double Read
Protruding osteophyte (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read
					VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read
					UNSCHEDULED	10FEB2016	8:16	N	Double Read
Relevant scoliosis	4_5	3_4	General		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read
					VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read
					UNSCHEDULED	10FEB2016	8:16	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read
					VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read
					UNSCHEDULED	10FEB2016	8:16	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5	3_4	Central Disc		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5	3_4	Central Disc		VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read
					VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
					UNSCHEDULED	05MAR2014	7:55	N	Double Read
					UNSCHEDULED	10FEB2016	8:16	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	27MAR2013	15:25	N	Double Read
					VISIT 3A	25JUN2013	14:20	N	Double Read
					VISIT 3K	28JUN2013	12:20	N	Single Read
					VISIT 3L	24JUL2013	12:56	N	Single Read
					VISIT 4	13AUG2013	11:04	N	Double Read
					VISIT 5	24SEP2013	10:58	N	Double Read
					VISIT 6	10DEC2013	10:07	N	Double Read
					VISIT 7	26JUN2014	8:56	N	Double Read
					VISIT 8	24JUN2015	14:05	N	Double Read
					VISIT 11	26JUN2018	13:24	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5	3_4	Caudal Disc	Anulus Fibrosus	Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20	111.67872	Single Read
					VISIT 3L	24JUL2013	12:56	116.37632	Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5	3_4	Caudal Disc	Anulus Fibrosus	UNSCHEDULED	10FEB2016	8:16		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	27MAR2013	15:25	87.59296	Double Read
					VISIT 3A	25JUN2013	14:20	93.86976	Double Read
					VISIT 3K	28JUN2013	12:20	87.86976	Single Read
					VISIT 3L	24JUL2013	12:56	96.73696	Single Read
					VISIT 4	13AUG2013	11:04	93.21376	Double Read
					VISIT 5	24SEP2013	10:58	96.61984	Double Read
					VISIT 6	10DEC2013	10:07	93.75632	Double Read
					VISIT 7	26JUN2014	8:56	102.00736	Double Read
					VISIT 8	24JUN2015	14:05	81.35216	Double Read
					VISIT 11	26JUN2018	13:24	82.89584	Double Read
					UNSCHEDULED	05MAR2014	7:55	96.99616	Double Read
					UNSCHEDULED	10FEB2016	8:16	85.00272	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5	3_4	Caudal Disc	Nucleus Pulposus	Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20	88.5824	Single Read
					VISIT 3L	24JUL2013	12:56	92.90688	Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5	3_4	Central Disc	Anulus Fibrosus	Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20		Single Read
					VISIT 3L	24JUL2013	12:56		Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5	3_4	Central Disc	Anulus Fibrosus	VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	27MAR2013	15:25	86.58176	Double Read
					VISIT 3A	25JUN2013	14:20	88.50368	Double Read
					VISIT 3K	28JUN2013	12:20	83.13184	Single Read
					VISIT 3L	24JUL2013	12:56	81.03072	Single Read
					VISIT 4	13AUG2013	11:04	80.6672	Double Read
					VISIT 5	24SEP2013	10:58	81.3824	Double Read
					VISIT 6	10DEC2013	10:07	87.09648	Double Read
					VISIT 7	26JUN2014	8:56	93.80128	Double Read
					VISIT 8	24JUN2015	14:05	84.05664	Double Read
					VISIT 11	26JUN2018	13:24	82.20528	Double Read
					UNSCHEDULED	05MAR2014	7:55	90.45216	Double Read
					UNSCHEDULED	10FEB2016	8:16	92.19344	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5	3_4	Central Disc	Nucleus Pulposus	Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20		Single Read
					VISIT 3L	24JUL2013	12:56		Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
T2 (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	3_4	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	27MAR2013	15:25		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	3_4	Cranial Disc, add. treated	Anulus Fibrosus	VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20		Single Read
					VISIT 3L	24JUL2013	12:56		Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
UNSCHEDULED	10FEB2016	8:16		Double Read					
T2 (ms) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	27MAR2013	15:25	92.36672	Double Read
					VISIT 3A	25JUN2013	14:20	91.82816	Double Read
					VISIT 3K	28JUN2013	12:20	89.67808	Single Read
					VISIT 3L	24JUL2013	12:56	89.0304	Single Read
					VISIT 4	13AUG2013	11:04	89.96224	Double Read
					VISIT 5	24SEP2013	10:58	91.05344	Double Read
					VISIT 6	10DEC2013	10:07	91.3792	Double Read
					VISIT 7	26JUN2014	8:56	92.42416	Double Read
					VISIT 8	24JUN2015	14:05	65.82208	Double Read
					VISIT 11	26JUN2018	13:24	98.91744	Double Read
					UNSCHEDULED	05MAR2014	7:55	93.552	Double Read
					UNSCHEDULED	10FEB2016	8:16	86.39088	Double Read
					T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	3_4	Cranial Disc, add. treated	Nucleus Pulposus
VISIT 3A	25JUN2013	14:20		Double Read					
VISIT 3K	28JUN2013	12:20		Single Read					
VISIT 3L	24JUL2013	12:56		Single Read					
VISIT 4	13AUG2013	11:04		Double Read					
VISIT 5	24SEP2013	10:58		Double Read					
VISIT 6	10DEC2013	10:07		Double Read					
VISIT 7	26JUN2014	8:56		Double Read					
VISIT 8	24JUN2015	14:05		Double Read					
VISIT 11	26JUN2018	13:24		Double Read					

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	3_4	Cranial Disc, add. treated	Nucleus Pulposus	UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5	3_4	Caudal Disc		Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20	equal	Double Read
					VISIT 3K	28JUN2013	12:20		Single Read
					VISIT 3L	24JUL2013	12:56	equal	Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5	3_4	Central Disc		Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20	higher	Double Read
					VISIT 3K	28JUN2013	12:20		Single Read
					VISIT 3L	24JUL2013	12:56	equal	Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	4_5	3_4	Cranial Disc, add. treated		Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	4_5	3_4	Cranial Disc, add. treated		VISIT 3K	28JUN2013	12:20	higher	Single Read
					VISIT 3L	24JUL2013	12:56	equal	Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5	3_4	Caudal Disc		Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20		Single Read
					VISIT 3L	24JUL2013	12:56		Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5	3_4	Central Disc		Baseline	27MAR2013	15:25	equal	Double Read
					VISIT 3A	25JUN2013	14:20	equal	Double Read
					VISIT 3K	28JUN2013	12:20	lower	Single Read
					VISIT 3L	24JUL2013	12:56	lower	Single Read
					VISIT 4	13AUG2013	11:04	lower	Double Read
					VISIT 5	24SEP2013	10:58	lower	Double Read
					VISIT 6	10DEC2013	10:07	lower	Double Read
					VISIT 7	26JUN2014	8:56	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5	3_4	Central Disc		VISIT 8	24JUN2015	14:05	lower	Double Read
					VISIT 11	26JUN2018	13:24	equal	Double Read
					UNSCHEDULED	05MAR2014	7:55	lower	Double Read
					UNSCHEDULED	10FEB2016	8:16	equal	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, add. treated,)	4_5	3_4	Cranial Disc, add. treated		Baseline	27MAR2013	15:25	lower	Double Read
					VISIT 3A	25JUN2013	14:20	lower	Double Read
					VISIT 3K	28JUN2013	12:20	equal	Single Read
					VISIT 3L	24JUL2013	12:56	equal	Single Read
					VISIT 4	13AUG2013	11:04	lower	Double Read
					VISIT 5	24SEP2013	10:58	lower	Double Read
					VISIT 6	10DEC2013	10:07	lower	Double Read
					VISIT 7	26JUN2014	8:56	lower	Double Read
					VISIT 8	24JUN2015	14:05	lower	Double Read
					VISIT 11	26JUN2018	13:24	higher	Double Read
					UNSCHEDULED	05MAR2014	7:55	lower	Double Read
					UNSCHEDULED	10FEB2016	8:16	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5	3_4	Caudal Disc		Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20		Single Read
					VISIT 3L	24JUL2013	12:56		Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5	3_4	Central Disc		Baseline	27MAR2013	15:25	lower	Double Read
					VISIT 3A	25JUN2013	14:20	lower	Double Read
					VISIT 3K	28JUN2013	12:20	equal	Single Read
					VISIT 3L	24JUL2013	12:56	equal	Single Read
					VISIT 4	13AUG2013	11:04	lower	Double Read
					VISIT 5	24SEP2013	10:58	lower	Double Read
					VISIT 6	10DEC2013	10:07	lower	Double Read
					VISIT 7	26JUN2014	8:56	equal	Double Read
					VISIT 8	24JUN2015	14:05	higher	Double Read
					VISIT 11	26JUN2018	13:24	higher	Double Read
					UNSCHEDULED	05MAR2014	7:55	equal	Double Read
					UNSCHEDULED	10FEB2016	8:16	higher	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, add. treated,)	4_5	3_4	Cranial Disc, add. treated		Baseline	27MAR2013	15:25	lower	Double Read
					VISIT 3A	25JUN2013	14:20	lower	Double Read
					VISIT 3K	28JUN2013	12:20	lower	Single Read
					VISIT 3L	24JUL2013	12:56	lower	Single Read
					VISIT 4	13AUG2013	11:04	lower	Double Read
					VISIT 5	24SEP2013	10:58	lower	Double Read
					VISIT 6	10DEC2013	10:07	lower	Double Read
					VISIT 7	26JUN2014	8:56	equal	Double Read
					VISIT 8	24JUN2015	14:05	equal	Double Read
					VISIT 11	26JUN2018	13:24	higher	Double Read
					UNSCHEDULED	05MAR2014	7:55	equal	Double Read
					UNSCHEDULED	10FEB2016	8:16	equal	Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5	3_4	Caudal Disc		Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20	equal	Single Read
					VISIT 3L	24JUL2013	12:56	equal	Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5	3_4	Caudal Disc		VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5	3_4	Central Disc		Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20	equal	Single Read
					VISIT 3L	24JUL2013	12:56	equal	Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, add. treated,)	4_5	3_4	Cranial Disc, add. treated		Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20	equal	Single Read
					VISIT 3L	24JUL2013	12:56	equal	Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5	3_4	Caudal Disc	Anulus Fibrosus	Baseline	27MAR2013	15:25		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5	3_4	Caudal Disc	Anulus Fibrosus	VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20	19.5635128249	Single Read
					VISIT 3L	24JUL2013	12:56	20.7050110413	Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	27MAR2013	15:25	22.8634618651	Double Read
					VISIT 3A	25JUN2013	14:20	21.4647868184	Double Read
					VISIT 3K	28JUN2013	12:20	11.7547137761	Single Read
					VISIT 3L	24JUL2013	12:56	9.90075760149	Single Read
					VISIT 4	13AUG2013	11:04	31.3061321556	Double Read
					VISIT 5	24SEP2013	10:58	25.4426363173	Double Read
					VISIT 6	10DEC2013	10:07	21.2480380499	Double Read
					VISIT 7	26JUN2014	8:56	32.826567012	Double Read
					VISIT 8	24JUN2015	14:05	7.58261933073	Double Read
					VISIT 11	26JUN2018	13:24	2.65111601835	Double Read
					UNSCHEDULED	05MAR2014	7:55	28.3918464414	Double Read
					UNSCHEDULED	10FEB2016	8:16	7.08031255308	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5	3_4	Caudal Disc	Nucleus Pulposus	Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20	12.6229182945	Single Read
					VISIT 3L	24JUL2013	12:56	4.85816205198	Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5	3_4	Central Disc	Anulus Fibrosus	Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20		Single Read
					VISIT 3L	24JUL2013	12:56		Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	27MAR2013	15:25	19.8858501783	Double Read
					VISIT 3A	25JUN2013	14:20	19.9174452183	Double Read
					VISIT 3K	28JUN2013	12:20	12.7242942076	Single Read
					VISIT 3L	24JUL2013	12:56	6.78036351282	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	VISIT 4	13AUG2013	11:04	14.903889927	Double Read
					VISIT 5	24SEP2013	10:58	12.300112111	Double Read
					VISIT 6	10DEC2013	10:07	18.457414642	Double Read
					VISIT 7	26JUN2014	8:56	18.939901477	Double Read
					VISIT 8	24JUN2015	14:05	3.7321963648	Double Read
					VISIT 11	26JUN2018	13:24	6.4093358247	Double Read
					UNSCHEDULED	05MAR2014	7:55	16.898658060	Double Read
					UNSCHEDULED	10FEB2016	8:16	7.3224324783	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5	3_4	Central Disc	Nucleus Pulposus	Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20		Single Read
					VISIT 3L	24JUL2013	12:56		Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	3_4	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20		Single Read
					VISIT 3L	24JUL2013	12:56		Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	3_4	Cranial Disc, add. treated	Anulus Fibrosus	VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	27MAR2013	15:25	21.932325462	Double Read
					VISIT 3A	25JUN2013	14:20	17.925802615	Double Read
					VISIT 3K	28JUN2013	12:20	14.058773568	Single Read
					VISIT 3L	24JUL2013	12:56	9.5908816035	Single Read
					VISIT 4	13AUG2013	11:04	20.537591302	Double Read
					VISIT 5	24SEP2013	10:58	18.886699507	Double Read
					VISIT 6	10DEC2013	10:07	19.437064718	Double Read
					VISIT 7	26JUN2014	8:56	17.178528962	Double Read
					VISIT 8	24JUN2015	14:05	4.5863767623	Double Read
					VISIT 11	26JUN2018	13:24	7.0541464243	Double Read
					UNSCHEDULED	05MAR2014	7:55	15.828503482	Double Read
					UNSCHEDULED	10FEB2016	8:16	5.5036521148	Double Read
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	3_4	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20		Single Read
					VISIT 3L	24JUL2013	12:56		Single Read
					VISIT 4	13AUG2013	11:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	3_4	Cranial Disc, add. treated	Nucleus Pulposus	VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5	3_4	Caudal Disc	Anulus Fibrosus	Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20	9808	Single Read
					VISIT 3L	24JUL2013	12:56	9022	Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	27MAR2013	15:25	15208.0	Double Read
					VISIT 3A	25JUN2013	14:20	13896.5	Double Read
					VISIT 3K	28JUN2013	12:20	12497	Single Read
					VISIT 3L	24JUL2013	12:56	12339	Single Read
					VISIT 4	13AUG2013	11:04	13534.0	Double Read
					VISIT 5	24SEP2013	10:58	14931.0	Double Read
					VISIT 6	10DEC2013	10:07	14804.5	Double Read
					VISIT 7	26JUN2014	8:56	12242.5	Double Read
					VISIT 8	24JUN2015	14:05	11294.0	Double Read
					VISIT 11	26JUN2018	13:24	11416.0	Double Read
					UNSCHEDULED	05MAR2014	7:55	14143.5	Double Read
					UNSCHEDULED	10FEB2016	8:16	11470.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5	3_4	Caudal Disc	Nucleus Pulposus	Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20	2689	Single Read
					VISIT 3L	24JUL2013	12:56	3317	Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5	3_4	Central Disc	Anulus Fibrosus	Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20		Single Read
					VISIT 3L	24JUL2013	12:56		Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	27MAR2013	15:25	18660.5	Double Read
					VISIT 3A	25JUN2013	14:20	19643.0	Double Read
					VISIT 3K	28JUN2013	12:20	19153	Single Read
					VISIT 3L	24JUL2013	12:56	15764	Single Read
					VISIT 4	13AUG2013	11:04	18617.0	Double Read
					VISIT 5	24SEP2013	10:58	20506.5	Double Read
					VISIT 6	10DEC2013	10:07	19977.5	Double Read
					VISIT 7	26JUN2014	8:56	18556.5	Double Read
					VISIT 8	24JUN2015	14:05	16067.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	VISIT 11	26JUN2018	13:24	13632.5	Double Read
					UNSCHEDULED	05MAR2014	7:55	19963.5	Double Read
					UNSCHEDULED	10FEB2016	8:16	16667.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5	3_4	Central Disc	Nucleus Pulposus	Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20		Single Read
					VISIT 3L	24JUL2013	12:56		Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	3_4	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20		Single Read
					VISIT 3L	24JUL2013	12:56		Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	27MAR2013	15:25	18320.5	Double Read
					VISIT 3A	25JUN2013	14:20	16595.0	Double Read
					VISIT 3K	28JUN2013	12:20	16678	Single Read
					VISIT 3L	24JUL2013	12:56	13940	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0203 Age=50 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	VISIT 4	13AUG2013	11:04	15532.0	Double Read
					VISIT 5	24SEP2013	10:58	17593.0	Double Read
					VISIT 6	10DEC2013	10:07	17536.0	Double Read
					VISIT 7	26JUN2014	8:56	15087.0	Double Read
					VISIT 8	24JUN2015	14:05	16285.5	Double Read
					VISIT 11	26JUN2018	13:24	13018.0	Double Read
					UNSCHEDULED	05MAR2014	7:55	16990.0	Double Read
					UNSCHEDULED	10FEB2016	8:16	16244.5	Double Read
Volume (mm^3) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	3_4	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	27MAR2013	15:25		Double Read
					VISIT 3A	25JUN2013	14:20		Double Read
					VISIT 3K	28JUN2013	12:20		Single Read
					VISIT 3L	24JUL2013	12:56		Single Read
					VISIT 4	13AUG2013	11:04		Double Read
					VISIT 5	24SEP2013	10:58		Double Read
					VISIT 6	10DEC2013	10:07		Double Read
					VISIT 7	26JUN2014	8:56		Double Read
					VISIT 8	24JUN2015	14:05		Double Read
					VISIT 11	26JUN2018	13:24		Double Read
					UNSCHEDULED	05MAR2014	7:55		Double Read
					UNSCHEDULED	10FEB2016	8:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0204 Age=35 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	17APR2013	16:39		Single Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	17APR2013	16:39	4	Single Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17APR2013	16:39	4	Single Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	17APR2013	16:39		Single Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	17APR2013	16:39	N	Single Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17APR2013	16:39	N	Single Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	17APR2013	16:39		Single Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	17APR2013	16:39	Y	Single Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17APR2013	16:39	N	Single Read
Extradiscal fluid collection	5_S		General		Baseline	17APR2013	16:39	N	Single Read
Fracture	5_S		General		Baseline	17APR2013	16:39	N	Single Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	17APR2013	16:39		Single Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	17APR2013	16:39	13.20	Single Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	17APR2013	16:39	12.30	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0204 Age=35 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	17APR2013	16:39		Single Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	17APR2013	16:39	8.927	Single Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	17APR2013	16:39	10.6865	Single Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	17APR2013	16:39		Single Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	17APR2013	16:39	N	Single Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17APR2013	16:39	N	Single Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	17APR2013	16:39		Single Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	17APR2013	16:39	N	Single Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17APR2013	16:39	N	Single Read
Normal lordotic LS	5_S		General		Baseline	17APR2013	16:39	Y	Single Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	17APR2013	16:39		Single Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	17APR2013	16:39	2	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0204 Age=35 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17APR2013	16:39	0	Single Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	17APR2013	16:39		Single Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	17APR2013	16:39	N	Single Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17APR2013	16:39	N	Single Read
Relevant scoliosis	5_S		General		Baseline	17APR2013	16:39	N	Single Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	17APR2013	16:39		Single Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	17APR2013	16:39	N	Single Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17APR2013	16:39	N	Single Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	17APR2013	16:39		Single Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	17APR2013	16:39		Single Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	17APR2013	16:39		Single Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	17APR2013	16:39		Single Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	17APR2013	16:39	90.2048	Single Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	17APR2013	16:39		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0204 Age=35 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	17APR2013	16:39		Single Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	17APR2013	16:39	86.59904	Single Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	17APR2013	16:39		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	17APR2013	16:39		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	17APR2013	16:39		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	17APR2013	16:39		Single Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	17APR2013	16:39		Single Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	17APR2013	16:39		Single Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	17APR2013	16:39		Single Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	17APR2013	16:39		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0204 Age=35 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	17APR2013	16:39	equal	Single Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	17APR2013	16:39		Single Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	17APR2013	16:39		Single Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	17APR2013	16:39		Single Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	17APR2013	16:39		Single Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	17APR2013	16:39		Single Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	17APR2013	16:39		Single Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	17APR2013	16:39		Single Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	17APR2013	16:39		Single Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	17APR2013	16:39	13.6160353321	Single Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	17APR2013	16:39		Single Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	17APR2013	16:39		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0204 Age=35 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	17APR2013	16:39	11.3845558009	Single Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	17APR2013	16:39		Single Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	17APR2013	16:39		Single Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	17APR2013	16:39		Single Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	17APR2013	16:39		Single Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	17APR2013	16:39		Single Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	17APR2013	16:39	14705	Single Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	17APR2013	16:39		Single Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	17APR2013	16:39		Single Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	17APR2013	16:39	13998	Single Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	17APR2013	16:39		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	18APR2013	8:11	3	Double Read
					VISIT 3A	30JUL2013	16:32	3	Double Read
					VISIT 3K	02AUG2013	7:48	3	Single Read
					VISIT 3L	21AUG2013	15:56	3	Single Read
					VISIT 4	17SEP2013	13:08	3	Double Read
					VISIT 5	28OCT2013	10:57	3	Double Read
					VISIT 6	23JAN2014	12:13	3	Double Read
					VISIT 7	12AUG2014	12:21	3	Double Read
					VISIT 8	21AUG2015	9:08	4	Double Read
					VISIT 11	28AUG2018	14:18	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18APR2013	8:11	3	Double Read
					VISIT 3A	30JUL2013	16:32	3	Double Read
					VISIT 3K	02AUG2013	7:48	3	Single Read
					VISIT 3L	21AUG2013	15:56	3	Single Read
					VISIT 4	17SEP2013	13:08	3	Double Read
					VISIT 5	28OCT2013	10:57	3	Double Read
					VISIT 6	23JAN2014	12:13	3	Double Read
					VISIT 7	12AUG2014	12:21	2	Double Read
					VISIT 8	21AUG2015	9:08	3	Double Read
					VISIT 11	28AUG2018	14:18	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	18APR2013	8:11		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	18APR2013	8:11	N	Double Read
					VISIT 3A	30JUL2013	16:32	N	Double Read
					VISIT 3K	02AUG2013	7:48	N	Single Read
					VISIT 3L	21AUG2013	15:56	N	Single Read
					VISIT 4	17SEP2013	13:08	N	Double Read
					VISIT 5	28OCT2013	10:57	N	Double Read
					VISIT 6	23JAN2014	12:13	N	Double Read
					VISIT 7	12AUG2014	12:21	N	Double Read
					VISIT 8	21AUG2015	9:08	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18APR2013	8:11	N	Double Read
					VISIT 3A	30JUL2013	16:32	N	Double Read
					VISIT 3K	02AUG2013	7:48	N	Single Read
					VISIT 3L	21AUG2013	15:56	N	Single Read
					VISIT 4	17SEP2013	13:08	N	Double Read
					VISIT 5	28OCT2013	10:57	N	Double Read
					VISIT 6	23JAN2014	12:13	N	Double Read
					VISIT 7	12AUG2014	12:21	N	Double Read
					VISIT 8	21AUG2015	9:08	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32	N	Double Read
					VISIT 3K	02AUG2013	7:48		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	18APR2013	8:11	Y	Double Read
					VISIT 3A	30JUL2013	16:32	N	Double Read
					VISIT 3K	02AUG2013	7:48	Y	Single Read
					VISIT 3L	21AUG2013	15:56	Y	Single Read
					VISIT 4	17SEP2013	13:08	Y	Double Read
					VISIT 5	28OCT2013	10:57	Y	Double Read
					VISIT 6	23JAN2014	12:13	N	Double Read
					VISIT 7	12AUG2014	12:21	N	Double Read
					VISIT 8	21AUG2015	9:08	Y	Double Read
					VISIT 11	28AUG2018	14:18	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18APR2013	8:11	N	Double Read
					VISIT 3A	30JUL2013	16:32	N	Double Read
					VISIT 3K	02AUG2013	7:48	Y	Single Read
					VISIT 3L	21AUG2013	15:56	N	Single Read
					VISIT 4	17SEP2013	13:08	Y	Double Read
					VISIT 5	28OCT2013	10:57	N	Double Read
					VISIT 6	23JAN2014	12:13	Y	Double Read
					VISIT 7	12AUG2014	12:21	N	Double Read
					VISIT 8	21AUG2015	9:08	Y	Double Read
					VISIT 11	28AUG2018	14:18	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	18APR2013	8:11	N	Double Read
					VISIT 3A	30JUL2013	16:32	N	Double Read
					VISIT 3K	02AUG2013	7:48	N	Single Read
					VISIT 3L	21AUG2013	15:56	N	Single Read
					VISIT 4	17SEP2013	13:08	N	Double Read
					VISIT 5	28OCT2013	10:57	N	Double Read
					VISIT 6	23JAN2014	12:13	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 7	12AUG2014	12:21	N	Double Read
					VISIT 8	21AUG2015	9:08	N	Double Read
					VISIT 11	28AUG2018	14:18	N	Double Read
Fracture	5_S		General		Baseline	18APR2013	8:11	N	Double Read
					VISIT 3A	30JUL2013	16:32	N	Double Read
					VISIT 3K	02AUG2013	7:48	N	Single Read
					VISIT 3L	21AUG2013	15:56	N	Single Read
					VISIT 4	17SEP2013	13:08	N	Double Read
					VISIT 5	28OCT2013	10:57	N	Double Read
					VISIT 6	23JAN2014	12:13	N	Double Read
					VISIT 7	12AUG2014	12:21	N	Double Read
					VISIT 8	21AUG2015	9:08	N	Double Read
					VISIT 11	28AUG2018	14:18	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18APR2013	8:11	12.665	Double Read
					VISIT 3A	30JUL2013	16:32	13.36	Double Read
					VISIT 3K	02AUG2013	7:48	11.00	Single Read
					VISIT 3L	21AUG2013	15:56	29.77	Single Read
					VISIT 4	17SEP2013	13:08	11.93	Double Read
					VISIT 5	28OCT2013	10:57	13.935	Double Read
					VISIT 6	23JAN2014	12:13	13.275	Double Read
					VISIT 7	12AUG2014	12:21	14.33	Double Read
					VISIT 8	21AUG2015	9:08	12.4	Double Read
					VISIT 11	28AUG2018	14:18	13.945	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18APR2013	8:11	17.175	Double Read
					VISIT 3A	30JUL2013	16:32	15.77	Double Read
					VISIT 3K	02AUG2013	7:48	14.18	Single Read
					VISIT 3L	21AUG2013	15:56	15.43	Single Read
					VISIT 4	17SEP2013	13:08	15.165	Double Read
					VISIT 5	28OCT2013	10:57	15.445	Double Read
					VISIT 6	23JAN2014	12:13	15.425	Double Read
					VISIT 7	12AUG2014	12:21	15.035	Double Read
					VISIT 8	21AUG2015	9:08	15.82	Double Read
					VISIT 11	28AUG2018	14:18	16.165	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18APR2013	8:11	8.92683	Double Read
					VISIT 3A	30JUL2013	16:32	8.31596	Double Read
					VISIT 3K	02AUG2013	7:48	9.17647	Single Read
					VISIT 3L	21AUG2013	15:56	7.59462	Single Read
					VISIT 4	17SEP2013	13:08	8.68171	Double Read
					VISIT 5	28OCT2013	10:57	8.084625	Double Read
					VISIT 6	23JAN2014	12:13	8.166905	Double Read
					VISIT 7	12AUG2014	12:21	8.467625	Double Read
					VISIT 8	21AUG2015	9:08	8.523335	Double Read
					VISIT 11	28AUG2018	14:18	9.29314	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18APR2013	8:11	12.25835	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 3A	30JUL2013	16:32	12.55055	Double Read
					VISIT 3K	02AUG2013	7:48	12.9976	Single Read
					VISIT 3L	21AUG2013	15:56	11.6162	Single Read
					VISIT 4	17SEP2013	13:08	12.45905	Double Read
					VISIT 5	28OCT2013	10:57	12.53175	Double Read
					VISIT 6	23JAN2014	12:13	12.2515	Double Read
					VISIT 7	12AUG2014	12:21	12.691	Double Read
					VISIT 8	21AUG2015	9:08	12.8456	Double Read
					VISIT 11	28AUG2018	14:18	12.84735	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	18APR2013	8:11	N	Double Read
					VISIT 3A	30JUL2013	16:32	N	Double Read
					VISIT 3K	02AUG2013	7:48	N	Single Read
					VISIT 3L	21AUG2013	15:56	N	Single Read
					VISIT 4	17SEP2013	13:08	N	Double Read
					VISIT 5	28OCT2013	10:57	N	Double Read
					VISIT 6	23JAN2014	12:13	Y	Double Read
					VISIT 7	12AUG2014	12:21	N	Double Read
					VISIT 8	21AUG2015	9:08	N	Double Read
					VISIT 11	28AUG2018	14:18	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18APR2013	8:11	N	Double Read
					VISIT 3A	30JUL2013	16:32	N	Double Read
					VISIT 3K	02AUG2013	7:48	N	Single Read
					VISIT 3L	21AUG2013	15:56	N	Single Read
					VISIT 4	17SEP2013	13:08	N	Double Read
					VISIT 5	28OCT2013	10:57	N	Double Read
					VISIT 6	23JAN2014	12:13	N	Double Read
					VISIT 7	12AUG2014	12:21	N	Double Read
					VISIT 8	21AUG2015	9:08	N	Double Read
					VISIT 11	28AUG2018	14:18	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	18APR2013	8:11	N	Double Read
					VISIT 3A	30JUL2013	16:32	N	Double Read
					VISIT 3K	02AUG2013	7:48	N	Single Read
					VISIT 3L	21AUG2013	15:56	N	Single Read
					VISIT 4	17SEP2013	13:08	N	Double Read
					VISIT 5	28OCT2013	10:57	N	Double Read
					VISIT 6	23JAN2014	12:13	N	Double Read
					VISIT 7	12AUG2014	12:21	N	Double Read
					VISIT 8	21AUG2015	9:08	N	Double Read
					VISIT 11	28AUG2018	14:18	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18APR2013	8:11	N	Double Read
					VISIT 3A	30JUL2013	16:32	N	Double Read
					VISIT 3K	02AUG2013	7:48	N	Single Read
					VISIT 3L	21AUG2013	15:56	N	Single Read
					VISIT 4	17SEP2013	13:08	N	Double Read
					VISIT 5	28OCT2013	10:57	N	Double Read
					VISIT 6	23JAN2014	12:13	N	Double Read
					VISIT 7	12AUG2014	12:21	N	Double Read
					VISIT 8	21AUG2015	9:08	N	Double Read
					VISIT 11	28AUG2018	14:18	N	Double Read
Normal lordotic LS	5_S		General		Baseline	18APR2013	8:11	Y	Double Read
					VISIT 3A	30JUL2013	16:32	Y	Double Read
					VISIT 3K	02AUG2013	7:48	Y	Single Read
					VISIT 3L	21AUG2013	15:56	Y	Single Read
					VISIT 4	17SEP2013	13:08	Y	Double Read
					VISIT 5	28OCT2013	10:57	Y	Double Read
					VISIT 6	23JAN2014	12:13	Y	Double Read
					VISIT 7	12AUG2014	12:21	Y	Double Read
					VISIT 8	21AUG2015	9:08	Y	Double Read
					VISIT 11	28AUG2018	14:18	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	18APR2013	8:11	0	Double Read
					VISIT 3A	30JUL2013	16:32	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 3K	02AUG2013	7:48	0	Single Read
					VISIT 3L	21AUG2013	15:56	0	Single Read
					VISIT 4	17SEP2013	13:08	0	Double Read
					VISIT 5	28OCT2013	10:57	0	Double Read
					VISIT 6	23JAN2014	12:13	0	Double Read
					VISIT 7	12AUG2014	12:21	0	Double Read
					VISIT 8	21AUG2015	9:08	0	Double Read
					VISIT 11	28AUG2018	14:18	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18APR2013	8:11	0	Double Read
					VISIT 3A	30JUL2013	16:32	0	Double Read
					VISIT 3K	02AUG2013	7:48	0	Single Read
					VISIT 3L	21AUG2013	15:56	0	Single Read
					VISIT 4	17SEP2013	13:08	0	Double Read
					VISIT 5	28OCT2013	10:57	0	Double Read
					VISIT 6	23JAN2014	12:13	0	Double Read
					VISIT 7	12AUG2014	12:21	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 8	21AUG2015	9:08	0	Double Read
					VISIT 11	28AUG2018	14:18	0	Double Read
					Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
					Baseline	18APR2013	8:11	N	Double Read
					VISIT 3A	30JUL2013	16:32	N	Double Read
					VISIT 3K	02AUG2013	7:48	N	Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 5	28OCT2013	10:57	N	Double Read
					VISIT 6	23JAN2014	12:13	N	Double Read
					VISIT 7	12AUG2014	12:21	N	Double Read
					VISIT 8	21AUG2015	9:08	N	Double Read
					VISIT 11	28AUG2018	14:18	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18APR2013	8:11	N	Double Read
					VISIT 3A	30JUL2013	16:32	N	Double Read
					VISIT 3K	02AUG2013	7:48	N	Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08	N	Double Read
					VISIT 5	28OCT2013	10:57	N	Double Read
					VISIT 6	23JAN2014	12:13	N	Double Read
					VISIT 7	12AUG2014	12:21	N	Double Read
					VISIT 8	21AUG2015	9:08	N	Double Read
					VISIT 11	28AUG2018	14:18	N	Double Read
Relevant scoliosis	5_S		General		Baseline	18APR2013	8:11	N	Double Read
					VISIT 3A	30JUL2013	16:32	N	Double Read
					VISIT 3K	02AUG2013	7:48	N	Single Read
					VISIT 3L	21AUG2013	15:56	N	Single Read
					VISIT 4	17SEP2013	13:08	N	Double Read
					VISIT 5	28OCT2013	10:57	N	Double Read
					VISIT 6	23JAN2014	12:13	N	Double Read
					VISIT 7	12AUG2014	12:21	N	Double Read
					VISIT 8	21AUG2015	9:08	N	Double Read
					VISIT 11	28AUG2018	14:18	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	18APR2013	8:11	N	Double Read
					VISIT 3A	30JUL2013	16:32	N	Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56	N	Single Read
					VISIT 4	17SEP2013	13:08	N	Double Read
					VISIT 5	28OCT2013	10:57	N	Double Read
					VISIT 6	23JAN2014	12:13	N	Double Read
					VISIT 7	12AUG2014	12:21	N	Double Read
					VISIT 8	21AUG2015	9:08	N	Double Read
					VISIT 11	28AUG2018	14:18	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18APR2013	8:11	N	Double Read
					VISIT 3A	30JUL2013	16:32	N	Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56	N	Single Read
					VISIT 4	17SEP2013	13:08	N	Double Read
					VISIT 5	28OCT2013	10:57	N	Double Read
					VISIT 6	23JAN2014	12:13	N	Double Read
					VISIT 7	12AUG2014	12:21	N	Double Read
					VISIT 8	21AUG2015	9:08	N	Double Read
					VISIT 11	28AUG2018	14:18	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 11	28AUG2018	14:18		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48	120.41696	Single Read
					VISIT 3L	21AUG2013	15:56	119.75392	Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18APR2013	8:11	86.55648	Double Read
					VISIT 3A	30JUL2013	16:32	89.40784	Double Read
					VISIT 3K	02AUG2013	7:48	96.82688	Single Read
					VISIT 3L	21AUG2013	15:56	80.41408	Single Read
					VISIT 4	17SEP2013	13:08	80.19808	Double Read
					VISIT 5	28OCT2013	10:57	82.49648	Double Read
					VISIT 6	23JAN2014	12:13	84.0456	Double Read
					VISIT 7	12AUG2014	12:21	89.53088	Double Read
					VISIT 8	21AUG2015	9:08	52.323472	Double Read
					VISIT 11	28AUG2018	14:18	62.91792	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48	106.3536	Single Read
					VISIT 3L	21AUG2013	15:56	84.09504	Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48	120.41792	Single Read
					VISIT 3L	21AUG2013	15:56	119.75456	Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18APR2013	8:11	95.53264	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 3A	30JUL2013	16:32	90.52272	Double Read
					VISIT 3K	02AUG2013	7:48	94.10496	Single Read
					VISIT 3L	21AUG2013	15:56	84.82912	Single Read
					VISIT 4	17SEP2013	13:08	85.4432	Double Read
					VISIT 5	28OCT2013	10:57	86.78064	Double Read
					VISIT 6	23JAN2014	12:13	87.72272	Double Read
					VISIT 7	12AUG2014	12:21	90.9344	Double Read
					VISIT 8	21AUG2015	9:08	63.17616	Double Read
					VISIT 11	28AUG2018	14:18	66.28432	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48	98.10912	Single Read
					VISIT 3L	21AUG2013	15:56	80.78368	Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48	equal	Single Read
					VISIT 3L	21AUG2013	15:56	equal	Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48	equal	Single Read
					VISIT 3L	21AUG2013	15:56	equal	Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48	equal	Single Read
					VISIT 3L	21AUG2013	15:56	equal	Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	18APR2013	8:11	equal	Double Read
					VISIT 3A	30JUL2013	16:32	equal	Double Read
					VISIT 3K	02AUG2013	7:48	equal	Single Read
					VISIT 3L	21AUG2013	15:56	lower	Single Read
					VISIT 4	17SEP2013	13:08	lower	Double Read
					VISIT 5	28OCT2013	10:57	lower	Double Read
					VISIT 6	23JAN2014	12:13	lower	Double Read
					VISIT 7	12AUG2014	12:21	lower	Double Read
					VISIT 8	21AUG2015	9:08	lower	Double Read
					VISIT 11	28AUG2018	14:18	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48	equal	Single Read
					VISIT 3L	21AUG2013	15:56	equal	Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48	equal	Single Read
					VISIT 3L	21AUG2013	15:56	equal	Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48	equal	Single Read
					VISIT 3L	21AUG2013	15:56	equal	Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48	18.8845931714	Single Read
					VISIT 3L	21AUG2013	15:56	18.8816035332	Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18APR2013	8:11	24.2901307967	Double Read
					VISIT 3A	30JUL2013	16:32	15.905513844	Double Read
					VISIT 3K	02AUG2013	7:48	14.6160693052	Single Read
					VISIT 3L	21AUG2013	15:56	8.18162051979	Single Read
					VISIT 4	17SEP2013	13:08	19.2416510956	Double Read
					VISIT 5	28OCT2013	10:57	15.4399932053	Double Read
					VISIT 6	23JAN2014	12:13	15.6344487855	Double Read
					VISIT 7	12AUG2014	12:21	17.5836453202	Double Read
					VISIT 8	21AUG2015	9:08	3.41996262953	Double Read
					VISIT 11	28AUG2018	14:18	7.75073212163	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48	12.117098692	Single Read
					VISIT 3L	21AUG2013	15:56	8.1131713946	Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48	18.8852726346	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	VISIT 3L	21AUG2013	15:56	18.8816035332	Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18APR2013	8:11	20.7137761168	Double Read
					VISIT 3A	30JUL2013	16:32	19.2403601155	Double Read
					VISIT 3K	02AUG2013	7:48	12.230338033	Single Read
					VISIT 3L	21AUG2013	15:56	15.8245625955	Single Read
					VISIT 4	17SEP2013	13:08	16.4914557499	Double Read
					VISIT 5	28OCT2013	10:57	19.4401902497	Double Read
					VISIT 6	23JAN2014	12:13	17.9739086122	Double Read
					VISIT 7	12AUG2014	12:21	16.0520197045	Double Read
					VISIT 8	21AUG2015	9:08	13.1794258536	Double Read
					VISIT 11	28AUG2018	14:18	9.86766094785	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48	9.11099031765	Single Read
					VISIT 3L	21AUG2013	15:56	12.1284185493	Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48		Single Read
					VISIT 3L	21AUG2013	15:56		Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48	8433	Single Read
					VISIT 3L	21AUG2013	15:56	3293	Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18APR2013	8:11	12936.5	Double Read
					VISIT 3A	30JUL2013	16:32	11900.0	Double Read
					VISIT 3K	02AUG2013	7:48	11920	Single Read
					VISIT 3L	21AUG2013	15:56	10158	Single Read
					VISIT 4	17SEP2013	13:08	11798.0	Double Read
					VISIT 5	28OCT2013	10:57	12277.5	Double Read
					VISIT 6	23JAN2014	12:13	13033.0	Double Read
					VISIT 7	12AUG2014	12:21	13236.5	Double Read
					VISIT 8	21AUG2015	9:08	10895.0	Double Read
					VISIT 11	28AUG2018	14:18	10213.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48	3487	Single Read
					VISIT 3L	21AUG2013	15:56	6865	Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48	10464	Single Read
					VISIT 3L	21AUG2013	15:56	9396	Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read
					VISIT 11	28AUG2018	14:18		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18APR2013	8:11	19855.5	Double Read
					VISIT 3A	30JUL2013	16:32	18193.0	Double Read
					VISIT 3K	02AUG2013	7:48	16936	Single Read
					VISIT 3L	21AUG2013	15:56	15105	Single Read
					VISIT 4	17SEP2013	13:08	17890.0	Double Read
					VISIT 5	28OCT2013	10:57	18425.5	Double Read
					VISIT 6	23JAN2014	12:13	19327.0	Double Read
					VISIT 7	12AUG2014	12:21	19411.0	Double Read
					VISIT 8	21AUG2015	9:08	17283.5	Double Read
					VISIT 11	28AUG2018	14:18	15507.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	18APR2013	8:11		Double Read
					VISIT 3A	30JUL2013	16:32		Double Read
					VISIT 3K	02AUG2013	7:48	6472	Single Read
					VISIT 3L	21AUG2013	15:56	5709	Single Read
					VISIT 4	17SEP2013	13:08		Double Read
					VISIT 5	28OCT2013	10:57		Double Read
					VISIT 6	23JAN2014	12:13		Double Read
					VISIT 7	12AUG2014	12:21		Double Read
					VISIT 8	21AUG2015	9:08		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0205 Age=45 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	28AUG2018	14:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	01JUL2013	9:30	3	Double Read
					VISIT 3A	08OCT2013	7:39	2	Double Read
					VISIT 3K	11OCT2013	13:02	3	Single Read
					VISIT 3L	29OCT2013	9:15	3	Single Read
					VISIT 4	20NOV2013	10:34	3	Double Read
					VISIT 5	03JAN2014	9:59	3	Double Read
					VISIT 6	07MAR2014	9:08	3	Double Read
					VISIT 7	30JUL2014	7:44	2	Double Read
					VISIT 11	30AUG2018	11:29	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	01JUL2013	9:30	3	Double Read
					VISIT 3A	08OCT2013	7:39	3	Double Read
					VISIT 3K	11OCT2013	13:02	3	Single Read
					VISIT 3L	29OCT2013	9:15	3	Single Read
					VISIT 4	20NOV2013	10:34	3	Double Read
					VISIT 5	03JAN2014	9:59	3	Double Read
					VISIT 6	07MAR2014	9:08	3	Double Read
					VISIT 7	30JUL2014	7:44	3	Double Read
					VISIT 11	30AUG2018	11:29	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01JUL2013	9:30	2	Double Read
					VISIT 3A	08OCT2013	7:39	2	Double Read
					VISIT 3K	11OCT2013	13:02	2	Single Read
					VISIT 3L	29OCT2013	9:15	2	Single Read
					VISIT 4	20NOV2013	10:34	2	Double Read
					VISIT 5	03JAN2014	9:59	2	Double Read
					VISIT 6	07MAR2014	9:08	2	Double Read
					VISIT 7	30JUL2014	7:44	2	Double Read
					VISIT 11	30AUG2018	11:29	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		VISIT 4	20NOV2013	10:34	N	Double Read
					VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	N	Double Read
					VISIT 7	30JUL2014	7:44	N	Double Read
					VISIT 11	30AUG2018	11:29	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read
					VISIT 4	20NOV2013	10:34	N	Double Read
					VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	N	Double Read
					VISIT 7	30JUL2014	7:44	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read
					VISIT 4	20NOV2013	10:34	N	Double Read
					VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	N	Double Read
					VISIT 7	30JUL2014	7:44	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read
					VISIT 4	20NOV2013	10:34	N	Double Read
					VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	N	Double Read
					VISIT 7	30JUL2014	7:44	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 11	30AUG2018	11:29	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	01JUL2013	9:30	Y	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	Y	Single Read
					VISIT 3L	29OCT2013	9:15	Y	Single Read
					VISIT 4	20NOV2013	10:34	Y	Double Read
					VISIT 5	03JAN2014	9:59	Y	Double Read
					VISIT 6	07MAR2014	9:08	Y	Double Read
					VISIT 7	30JUL2014	7:44	Y	Double Read
					VISIT 11	30AUG2018	11:29	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read
					VISIT 4	20NOV2013	10:34	N	Double Read
					VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	N	Double Read
					VISIT 7	30JUL2014	7:44	N	Double Read
					VISIT 11	30AUG2018	11:29	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	Y	Single Read
					VISIT 3L	29OCT2013	9:15	Y	Single Read
					VISIT 4	20NOV2013	10:34	N	Double Read
					VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	N	Double Read
					VISIT 7	30JUL2014	7:44	N	Double Read
					VISIT 11	30AUG2018	11:29	N	Double Read
Fracture	4_5		General		Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read
					VISIT 4	20NOV2013	10:34	N	Double Read
					VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Fracture	4_5		General		VISIT 7	30JUL2014	7:44	N	Double Read
					VISIT 11	30AUG2018	11:29	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	01JUL2013	9:30	20.855	Double Read
					VISIT 3A	08OCT2013	7:39	13.735	Double Read
					VISIT 3K	11OCT2013	13:02	13.01	Single Read
					VISIT 3L	29OCT2013	9:15	12.65	Single Read
					VISIT 4	20NOV2013	10:34	13.27	Double Read
					VISIT 5	03JAN2014	9:59	13.93	Double Read
					VISIT 6	07MAR2014	9:08	14.515	Double Read
					VISIT 7	30JUL2014	7:44	13.68	Double Read
					VISIT 11	30AUG2018	11:29	12.82	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	01JUL2013	9:30	12.46	Double Read
					VISIT 3A	08OCT2013	7:39	12.98	Double Read
					VISIT 3K	11OCT2013	13:02	12.29	Single Read
					VISIT 3L	29OCT2013	9:15	14.55	Single Read
					VISIT 4	20NOV2013	10:34	12.185	Double Read
					VISIT 5	03JAN2014	9:59	15.415	Double Read
					VISIT 6	07MAR2014	9:08	15.005	Double Read
					VISIT 7	30JUL2014	7:44	13.295	Double Read
					VISIT 11	30AUG2018	11:29	11.43	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	01JUL2013	9:30	15.11	Double Read
					VISIT 3A	08OCT2013	7:39	14.64	Double Read
					VISIT 3K	11OCT2013	13:02	14.61	Single Read
					VISIT 3L	29OCT2013	9:15	14.71	Single Read
					VISIT 4	20NOV2013	10:34	15.23	Double Read
					VISIT 5	03JAN2014	9:59	16.27	Double Read
					VISIT 6	07MAR2014	9:08	15.235	Double Read
					VISIT 7	30JUL2014	7:44	14.215	Double Read
					VISIT 11	30AUG2018	11:29	14.915	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	01JUL2013	9:30	9.702895	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	VISIT 3A	08OCT2013	7:39	9.203245	Double Read
					VISIT 3K	11OCT2013	13:02	9.8824	Single Read
					VISIT 3L	29OCT2013	9:15	9.63954	Single Read
					VISIT 4	20NOV2013	10:34	9.55011	Double Read
					VISIT 5	03JAN2014	9:59	9.34968	Double Read
					VISIT 6	07MAR2014	9:08	9.198915	Double Read
					VISIT 7	30JUL2014	7:44	9.81309	Double Read
					VISIT 11	30AUG2018	11:29	9.47438	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	01JUL2013	9:30	8.2842	Double Read
					VISIT 3A	08OCT2013	7:39	8.01645	Double Read
					VISIT 3K	11OCT2013	13:02	8.29192	Single Read
					VISIT 3L	29OCT2013	9:15	8.4703	Single Read
					VISIT 4	20NOV2013	10:34	8.5015	Double Read
					VISIT 5	03JAN2014	9:59	8.418245	Double Read
					VISIT 6	07MAR2014	9:08	8.691055	Double Read
					VISIT 7	30JUL2014	7:44	8.155685	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	01JUL2013	9:30	13.3308	Double Read
					VISIT 3A	08OCT2013	7:39	13.43965	Double Read
					VISIT 3K	11OCT2013	13:02	13.7549	Single Read
					VISIT 3L	29OCT2013	9:15	13.9196	Single Read
					VISIT 4	20NOV2013	10:34	13.1213	Double Read
					VISIT 5	03JAN2014	9:59	12.48545	Double Read
					VISIT 6	07MAR2014	9:08	13.13875	Double Read
					VISIT 7	30JUL2014	7:44	13.3242	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		VISIT 4	20NOV2013	10:34	N	Double Read
					VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	N	Double Read
					VISIT 7	30JUL2014	7:44	N	Double Read
					VISIT 11	30AUG2018	11:29	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read
					VISIT 4	20NOV2013	10:34	N	Double Read
					VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	N	Double Read
					VISIT 7	30JUL2014	7:44	N	Double Read
					VISIT 11	30AUG2018	11:29	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read
					VISIT 4	20NOV2013	10:34	N	Double Read
					VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	N	Double Read
					VISIT 7	30JUL2014	7:44	N	Double Read
					VISIT 11	30AUG2018	11:29	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read
					VISIT 4	20NOV2013	10:34	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	N	Double Read
					VISIT 7	30JUL2014	7:44	N	Double Read
					VISIT 11	30AUG2018	11:29	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read
					VISIT 4	20NOV2013	10:34	N	Double Read
					VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	N	Double Read
					VISIT 7	30JUL2014	7:44	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 11	30AUG2018	11:29	N	Double Read
					Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read
					VISIT 4	20NOV2013	10:34	N	Double Read
					VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	N	Double Read
Normal lordotic LS	4_5		General		VISIT 7	30JUL2014	7:44	N	Double Read
					VISIT 11	30AUG2018	11:29	N	Double Read
					Baseline	01JUL2013	9:30	Y	Double Read
					VISIT 3A	08OCT2013	7:39	Y	Double Read
					VISIT 3K	11OCT2013	13:02	Y	Single Read
					VISIT 3L	29OCT2013	9:15	Y	Single Read
					VISIT 4	20NOV2013	10:34	Y	Double Read
					VISIT 5	03JAN2014	9:59	Y	Double Read
					VISIT 6	07MAR2014	9:08	Y	Double Read
					VISIT 7	30JUL2014	7:44	Y	Double Read
					VISIT 11	30AUG2018	11:29	Y	Double Read
					VISIT 11	30AUG2018	11:29	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	01JUL2013	9:30	0	Double Read
					VISIT 3A	08OCT2013	7:39	0	Double Read
					VISIT 3K	11OCT2013	13:02	0	Single Read
					VISIT 3L	29OCT2013	9:15	0	Single Read
					VISIT 4	20NOV2013	10:34	0	Double Read
					VISIT 5	03JAN2014	9:59	0	Double Read
					VISIT 6	07MAR2014	9:08	3	Double Read
					VISIT 7	30JUL2014	7:44	0	Double Read
					VISIT 11	30AUG2018	11:29	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	01JUL2013	9:30	0	Double Read
					VISIT 3A	08OCT2013	7:39	0	Double Read
					VISIT 3K	11OCT2013	13:02	2	Single Read
					VISIT 3L	29OCT2013	9:15	2	Single Read
					VISIT 4	20NOV2013	10:34	0	Double Read
					VISIT 5	03JAN2014	9:59	2	Double Read
					VISIT 6	07MAR2014	9:08	2	Double Read
					VISIT 7	30JUL2014	7:44	1	Double Read
					VISIT 11	30AUG2018	11:29	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01JUL2013	9:30	0	Double Read
					VISIT 3A	08OCT2013	7:39	0	Double Read
					VISIT 3K	11OCT2013	13:02	0	Single Read
					VISIT 3L	29OCT2013	9:15	0	Single Read
					VISIT 4	20NOV2013	10:34	0	Double Read
					VISIT 5	03JAN2014	9:59	0	Double Read
					VISIT 6	07MAR2014	9:08	0	Double Read
					VISIT 7	30JUL2014	7:44	0	Double Read
					VISIT 11	30AUG2018	11:29	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read
					VISIT 4	20NOV2013	10:34	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	Y	Double Read
					VISIT 7	30JUL2014	7:44	N	Double Read
					VISIT 11	30AUG2018	11:29	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read
					VISIT 4	20NOV2013	10:34	N	Double Read
					VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	Y	Double Read
					VISIT 7	30JUL2014	7:44	N	Double Read
					VISIT 11	30AUG2018	11:29	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read
					VISIT 4	20NOV2013	10:34	N	Double Read
					VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	N	Double Read
					VISIT 7	30JUL2014	7:44	N	Double Read
					VISIT 11	30AUG2018	11:29	N	Double Read
Relevant scoliosis	4_5		General		Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read
					VISIT 4	20NOV2013	10:34	N	Double Read
					VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	N	Double Read
					VISIT 7	30JUL2014	7:44	N	Double Read
					VISIT 11	30AUG2018	11:29	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	01JUL2013	9:30	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read
					VISIT 4	20NOV2013	10:34	N	Double Read
					VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	N	Double Read
					VISIT 7	30JUL2014	7:44	N	Double Read
					VISIT 11	30AUG2018	11:29	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read
					VISIT 4	20NOV2013	10:34	N	Double Read
					VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	N	Double Read
					VISIT 7	30JUL2014	7:44	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	01JUL2013	9:30	N	Double Read
					VISIT 3A	08OCT2013	7:39	N	Double Read
					VISIT 3K	11OCT2013	13:02	N	Single Read
					VISIT 3L	29OCT2013	9:15	N	Single Read
					VISIT 4	20NOV2013	10:34	N	Double Read
					VISIT 5	03JAN2014	9:59	N	Double Read
					VISIT 6	07MAR2014	9:08	N	Double Read
					VISIT 7	30JUL2014	7:44	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	116.6304	Single Read
					VISIT 3L	29OCT2013	9:15	96.92096	Single Read
					VISIT 4	20NOV2013	10:34		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	01JUL2013	9:30	92.69024	Double Read
					VISIT 3A	08OCT2013	7:39	92.42512	Double Read
					VISIT 3K	11OCT2013	13:02	90.2736	Single Read
					VISIT 3L	29OCT2013	9:15	91.21056	Single Read
					VISIT 4	20NOV2013	10:34	88.54704	Double Read
					VISIT 5	03JAN2014	9:59	88.93312	Double Read
					VISIT 6	07MAR2014	9:08	86.46992	Double Read
					VISIT 7	30JUL2014	7:44	85.76976	Double Read
					VISIT 11	30AUG2018	11:29	71.348	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	87.87936	Single Read
					VISIT 3L	29OCT2013	9:15	88.08768	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	116.63072	Single Read
					VISIT 3L	29OCT2013	9:15	116.95008	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	01JUL2013	9:30	93.66896	Double Read
					VISIT 3A	08OCT2013	7:39	87.23872	Double Read
					VISIT 3K	11OCT2013	13:02	100.34656	Single Read
					VISIT 3L	29OCT2013	9:15	95.81824	Single Read
					VISIT 4	20NOV2013	10:34	89.91568	Double Read
					VISIT 5	03JAN2014	9:59	93.12144	Double Read
					VISIT 6	07MAR2014	9:08	91.23776	Double Read
					VISIT 7	30JUL2014	7:44	85.89008	Double Read
					VISIT 11	30AUG2018	11:29	73.79936	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	103.91744	Single Read
					VISIT 3L	29OCT2013	9:15	94.7552	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	116.62528	Single Read
					VISIT 3L	29OCT2013	9:15	116.9472	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	01JUL2013	9:30	110.7808	Double Read
					VISIT 3A	08OCT2013	7:39	109.30272	Double Read
					VISIT 3K	11OCT2013	13:02	115.35904	Single Read
					VISIT 3L	29OCT2013	9:15	110.93504	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	VISIT 4	20NOV2013	10:34	110.84992	Double Read
					VISIT 5	03JAN2014	9:59	113.16432	Double Read
					VISIT 6	07MAR2014	9:08	106.75664	Double Read
					VISIT 7	30JUL2014	7:44	104.51232	Double Read
					VISIT 11	30AUG2018	11:29	80.00032	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	117.53376	Single Read
					VISIT 3L	29OCT2013	9:15	115.29664	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	equal	Single Read
					VISIT 3L	29OCT2013	9:15	equal	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	higher	Single Read
					VISIT 3L	29OCT2013	9:15	higher	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	equal	Single Read
					VISIT 3L	29OCT2013	9:15	equal	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02		Single Read
					VISIT 3L	29OCT2013	9:15		Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	01JUL2013	9:30	lower	Double Read
					VISIT 3A	08OCT2013	7:39	lower	Double Read
					VISIT 3K	11OCT2013	13:02	higher	Single Read
					VISIT 3L	29OCT2013	9:15	equal	Single Read
					VISIT 4	20NOV2013	10:34	equal	Double Read
					VISIT 5	03JAN2014	9:59	equal	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		VISIT 6	07MAR2014	9:08	equal	Double Read
					VISIT 7	30JUL2014	7:44	lower	Double Read
					VISIT 11	30AUG2018	11:29	equal	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02		Single Read
					VISIT 3L	29OCT2013	9:15		Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02		Single Read
					VISIT 3L	29OCT2013	9:15		Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	01JUL2013	9:30	lower	Double Read
					VISIT 3A	08OCT2013	7:39	lower	Double Read
					VISIT 3K	11OCT2013	13:02	equal	Single Read
					VISIT 3L	29OCT2013	9:15	equal	Single Read
					VISIT 4	20NOV2013	10:34	lower	Double Read
					VISIT 5	03JAN2014	9:59	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		VISIT 6	07MAR2014	9:08	lower	Double Read
					VISIT 7	30JUL2014	7:44	lower	Double Read
					VISIT 11	30AUG2018	11:29	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02		Single Read
					VISIT 3L	29OCT2013	9:15		Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	equal	Single Read
					VISIT 3L	29OCT2013	9:15	equal	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	higher	Single Read
					VISIT 3L	29OCT2013	9:15	higher	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 11	30AUG2018	11:29		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	equal	Single Read
					VISIT 3L	29OCT2013	9:15	equal	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	21.3756412434	Single Read
					VISIT 3L	29OCT2013	9:15	15.8824528622	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	01JUL2013	9:30	16.3145914727	Double Read
					VISIT 3A	08OCT2013	7:39	17.7151690165	Double Read
					VISIT 3K	11OCT2013	13:02	19.1090878206	Single Read
					VISIT 3L	29OCT2013	9:15	16.3826736878	Single Read
					VISIT 4	20NOV2013	10:34	15.5409546458	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	VISIT 5	03JAN2014	9:59	18.455444199	Double Read
					VISIT 6	07MAR2014	9:08	19.873483947	Double Read
					VISIT 7	30JUL2014	7:44	14.69764566	Double Read
					VISIT 11	30AUG2018	11:29	13.767623577	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	15.559707830	Single Read
					VISIT 3L	29OCT2013	9:15	14.563207066	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	21.373466961	Single Read
					VISIT 3L	29OCT2013	9:15	23.298522167	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	01JUL2013	9:30	11.143380329	Double Read
					VISIT 3A	08OCT2013	7:39	14.909937149	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3K	11OCT2013	13:02	14.3374893834	Single Read
					VISIT 3L	29OCT2013	9:15	10.8417598098	Single Read
					VISIT 4	20NOV2013	10:34	16.2284355359	Double Read
					VISIT 5	03JAN2014	9:59	21.3645659929	Double Read
					VISIT 6	07MAR2014	9:08	15.911262103	Double Read
					VISIT 7	30JUL2014	7:44	17.7737387464	Double Read
					VISIT 11	30AUG2018	11:29	8.26680482418	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	11.0567147953	Single Read
					VISIT 3L	29OCT2013	9:15	10.5090266689	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	21.3718362494	Single Read
					VISIT 3L	29OCT2013	9:15	23.3001528792	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
	VISIT 7	30JUL2014	7:44		Double Read				

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	VISIT 11	30AUG2018	11:29		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	01JUL2013	9:30	18.824596568	Double Read
					VISIT 3A	08OCT2013	7:39	21.925449295	Double Read
					VISIT 3K	11OCT2013	13:02	26.246713096	Single Read
					VISIT 3L	29OCT2013	9:15	11.673830473	Single Read
					VISIT 4	20NOV2013	10:34	24.533718362	Double Read
					VISIT 5	03JAN2014	9:59	20.400951248	Double Read
					VISIT 6	07MAR2014	9:08	15.198709019	Double Read
					VISIT 7	30JUL2014	7:44	28.199694241	Double Read
					VISIT 11	30AUG2018	11:29	6.2906947511	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	17.382979446	Single Read
					VISIT 3L	29OCT2013	9:15	11.461851537	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 3K	11OCT2013	13:02	6622	Single Read
					VISIT 3L	29OCT2013	9:15	8108	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	01JUL2013	9:30	12876.0	Double Read
					VISIT 3A	08OCT2013	7:39	13703.0	Double Read
					VISIT 3K	11OCT2013	13:02	12132	Single Read
					VISIT 3L	29OCT2013	9:15	12586	Single Read
					VISIT 4	20NOV2013	10:34	12977.0	Double Read
					VISIT 5	03JAN2014	9:59	13917.5	Double Read
					VISIT 6	07MAR2014	9:08	14733.5	Double Read
					VISIT 7	30JUL2014	7:44	13649.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	5510	Single Read
					VISIT 3L	29OCT2013	9:15	4478	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	8649	Single Read
					VISIT 3L	29OCT2013	9:15	10318	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	01JUL2013	9:30	13521.0	Double Read
					VISIT 3A	08OCT2013	7:39	14876.5	Double Read
					VISIT 3K	11OCT2013	13:02	12211	Single Read
					VISIT 3L	29OCT2013	9:15	13797	Single Read
					VISIT 4	20NOV2013	10:34	14728.0	Double Read
					VISIT 5	03JAN2014	9:59	17786.0	Double Read
					VISIT 6	07MAR2014	9:08	16759.0	Double Read
					VISIT 7	30JUL2014	7:44	16591.5	Double Read
					VISIT 11	30AUG2018	11:29	12283.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	3562	Single Read
					VISIT 3L	29OCT2013	9:15	3479	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	10729	Single Read
					VISIT 3L	29OCT2013	9:15	6856	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0206 Age=46 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	01JUL2013	9:30	21419.0	Double Read
					VISIT 3A	08OCT2013	7:39	21233.0	Double Read
					VISIT 3K	11OCT2013	13:02	18597	Single Read
					VISIT 3L	29OCT2013	9:15	17876	Single Read
					VISIT 4	20NOV2013	10:34	21155.5	Double Read
					VISIT 5	03JAN2014	9:59	22514.5	Double Read
					VISIT 6	07MAR2014	9:08	21904.0	Double Read
					VISIT 7	30JUL2014	7:44	20584.0	Double Read
					VISIT 11	30AUG2018	11:29	19628.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	01JUL2013	9:30		Double Read
					VISIT 3A	08OCT2013	7:39		Double Read
					VISIT 3K	11OCT2013	13:02	7868	Single Read
					VISIT 3L	29OCT2013	9:15	11020	Single Read
					VISIT 4	20NOV2013	10:34		Double Read
					VISIT 5	03JAN2014	9:59		Double Read
					VISIT 6	07MAR2014	9:08		Double Read
					VISIT 7	30JUL2014	7:44		Double Read
					VISIT 11	30AUG2018	11:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0207 Age=34 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	24JUL2013	8:33		Single Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	24JUL2013	8:33	4	Single Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	24JUL2013	8:33	2	Single Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	24JUL2013	8:33		Single Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	24JUL2013	8:33	N	Single Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	24JUL2013	8:33	N	Single Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	24JUL2013	8:33		Single Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	24JUL2013	8:33	Y	Single Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	24JUL2013	8:33	N	Single Read
Extradiscal fluid collection	5_S		General		Baseline	24JUL2013	8:33	N	Single Read
Fracture	5_S		General		Baseline	24JUL2013	8:33	N	Single Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	24JUL2013	8:33		Single Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	24JUL2013	8:33	12.35	Single Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	24JUL2013	8:33	12.62	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0207 Age=34 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	24JUL2013	8:33		Single Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	24JUL2013	8:33	9.73982	Single Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	24JUL2013	8:33	12.3674	Single Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	24JUL2013	8:33		Single Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	24JUL2013	8:33	N	Single Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	24JUL2013	8:33	N	Single Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	24JUL2013	8:33		Single Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	24JUL2013	8:33	N	Single Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	24JUL2013	8:33	N	Single Read
Normal lordotic LS	5_S		General		Baseline	24JUL2013	8:33	Y	Single Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	24JUL2013	8:33		Single Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	24JUL2013	8:33	0	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0207 Age=34 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	24JUL2013	8:33	0	Single Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	24JUL2013	8:33		Single Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	24JUL2013	8:33	N	Single Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	24JUL2013	8:33	N	Single Read
Relevant scoliosis	5_S		General		Baseline	24JUL2013	8:33	N	Single Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	24JUL2013	8:33		Single Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	24JUL2013	8:33	Y	Single Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	24JUL2013	8:33	N	Single Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	24JUL2013	8:33		Single Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	24JUL2013	8:33		Single Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	24JUL2013	8:33		Single Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	24JUL2013	8:33		Single Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	24JUL2013	8:33	89.80512	Single Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	24JUL2013	8:33		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0207 Age=34 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	24JUL2013	8:33	121.84416	Single Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	24JUL2013	8:33	133.64928	Single Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	24JUL2013	8:33	139.02368	Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	24JUL2013	8:33		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	24JUL2013	8:33		Single Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	24JUL2013	8:33		Single Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	24JUL2013	8:33		Single Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	24JUL2013	8:33		Single Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	24JUL2013	8:33		Single Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	24JUL2013	8:33		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0207 Age=34 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	24JUL2013	8:33	lower	Single Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	24JUL2013	8:33		Single Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	24JUL2013	8:33		Single Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	24JUL2013	8:33		Single Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	24JUL2013	8:33		Single Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	24JUL2013	8:33		Single Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	24JUL2013	8:33		Single Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	24JUL2013	8:33		Single Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	24JUL2013	8:33		Single Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	24JUL2013	8:33	12.0820927467	Single Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	24JUL2013	8:33		Single Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	24JUL2013	8:33	9.21050450144	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0207 Age=34 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	24JUL2013	8:33	12.3075522337	Single Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	24JUL2013	8:33	10.1898420248	Single Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	24JUL2013	8:33		Single Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	24JUL2013	8:33		Single Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	24JUL2013	8:33		Single Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	24JUL2013	8:33		Single Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	24JUL2013	8:33	12463	Single Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	24JUL2013	8:33		Single Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	24JUL2013	8:33	8697	Single Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	24JUL2013	8:33	13756	Single Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	24JUL2013	8:33	5059	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50	3	Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19	3	Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S	4_5	Central Disc		Baseline	11SEP2013	16:35	3	Double Read
					VISIT 3A	09DEC2013	16:35	3	Double Read
					VISIT 3K	12DEC2013	13:52	3	Single Read
					VISIT 3L	30DEC2013	10:18	3	Single Read
					VISIT 4	22JAN2014	12:50	3	Double Read
					VISIT 5	25MAR2014	10:58	3	Double Read
					VISIT 6	28MAY2014	13:19	3	Double Read
					VISIT 7	30DEC2014	9:25	2	Double Read
					VISIT 8	17DEC2015	13:39	2	Double Read
					VISIT 11	27DEC2018	10:14	2	Double Read
					UNSCHEDULED	17DEC2013	12:45	3	Double Read
					UNSCHEDULED	04SEP2015	10:31	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	11SEP2013	16:35	3	Double Read
					VISIT 3A	09DEC2013	16:35	4	Double Read
					VISIT 3K	12DEC2013	13:52	4	Single Read
					VISIT 3L	30DEC2013	10:18	4	Single Read
					VISIT 4	22JAN2014	12:50	3	Double Read
					VISIT 5	25MAR2014	10:58	3	Double Read
					VISIT 6	28MAY2014	13:19	4	Double Read
					VISIT 7	30DEC2014	9:25	2	Double Read
					VISIT 8	17DEC2015	13:39	3	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 11	27DEC2018	10:14	3	Double Read
					UNSCHEDULED	17DEC2013	12:45	4	Double Read
					UNSCHEDULED	04SEP2015	10:31	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	N	Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S	4_5	Central Disc		Baseline	11SEP2013	16:35	N	Double Read
					VISIT 3A	09DEC2013	16:35	N	Double Read
					VISIT 3K	12DEC2013	13:52	N	Single Read
					VISIT 3L	30DEC2013	10:18	N	Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	N	Double Read
					VISIT 7	30DEC2014	9:25	N	Double Read
					VISIT 8	17DEC2015	13:39	N	Double Read
					VISIT 11	27DEC2018	10:14	N	Double Read
					UNSCHEDULED	17DEC2013	12:45	N	Double Read
					UNSCHEDULED	04SEP2015	10:31	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	11SEP2013	16:35	N	Double Read
					VISIT 3A	09DEC2013	16:35	N	Double Read
					VISIT 3K	12DEC2013	13:52	N	Single Read
					VISIT 3L	30DEC2013	10:18	N	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	N	Double Read
					VISIT 7	30DEC2014	9:25	N	Double Read
					VISIT 8	17DEC2015	13:39	N	Double Read
					VISIT 11	27DEC2018	10:14	N	Double Read
					UNSCHEDULED	17DEC2013	12:45	N	Double Read
					UNSCHEDULED	04SEP2015	10:31	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	N	Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45	N	Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
					Baseline	11SEP2013	16:35	N	Double Read
					VISIT 3A	09DEC2013	16:35	N	Double Read
Dorsal disc extrusion (Central Disc)	5_S	4_5	Central Disc		VISIT 3K	12DEC2013	13:52	Y	Single Read
					VISIT 3L	30DEC2013	10:18	Y	Single Read
					VISIT 4	22JAN2014	12:50	Y	Double Read
					VISIT 5	25MAR2014	10:58	Y	Double Read
					VISIT 6	28MAY2014	13:19	Y	Double Read
					VISIT 7	30DEC2014	9:25	Y	Double Read
					VISIT 8	17DEC2015	13:39	Y	Double Read
					VISIT 11	27DEC2018	10:14	Y	Double Read
					UNSCHEDULED	17DEC2013	12:45	Y	Double Read
					UNSCHEDULED	04SEP2015	10:31	Y	Double Read
					Baseline	11SEP2013	16:35	N	Double Read
					VISIT 3A	09DEC2013	16:35	N	Double Read
					VISIT 3K	12DEC2013	13:52	Y	Single Read
					VISIT 3L	30DEC2013	10:18	Y	Single Read
Dorsal disc extrusion (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 3A	09DEC2013	16:35	N	Double Read
					VISIT 3K	12DEC2013	13:52	N	Single Read
					VISIT 3L	30DEC2013	10:18	N	Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	Y	Double Read
					VISIT 7	30DEC2014	9:25	N	Double Read
					VISIT 8	17DEC2015	13:39	N	Double Read
					VISIT 11	27DEC2018	10:14	N	Double Read
					UNSCHEDULED	17DEC2013	12:45	N	Double Read
Extradiscal fluid collection	5_S	4_5	General		UNSCHEDULED	04SEP2015	10:31	N	Double Read
					Baseline	11SEP2013	16:35	N	Double Read
					VISIT 3A	09DEC2013	16:35	N	Double Read
					VISIT 3K	12DEC2013	13:52	N	Single Read
					VISIT 3L	30DEC2013	10:18	Y	Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	Y	Double Read
					VISIT 7	30DEC2014	9:25	N	Double Read
					VISIT 8	17DEC2015	13:39	N	Double Read
Fracture	5_S	4_5	General		VISIT 11	27DEC2018	10:14	N	Double Read
					UNSCHEDULED	17DEC2013	12:45	N	Double Read
					UNSCHEDULED	04SEP2015	10:31	N	Double Read
					Baseline	11SEP2013	16:35	N	Double Read
					VISIT 3A	09DEC2013	16:35	N	Double Read
					VISIT 3K	12DEC2013	13:52	N	Single Read
					VISIT 3L	30DEC2013	10:18	N	Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	11SEP2013	16:35	16.155	Double Read
					VISIT 3A	09DEC2013	16:35	18.17	Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18	16.77	Single Read
					VISIT 4	22JAN2014	12:50	19.245	Double Read
					VISIT 5	25MAR2014	10:58	17.72	Double Read
					VISIT 6	28MAY2014	13:19	17.325	Double Read
					VISIT 7	30DEC2014	9:25	17.01	Double Read
					VISIT 8	17DEC2015	13:39	16.62	Double Read
					VISIT 11	27DEC2018	10:14	16.485	Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31	17.375	Double Read
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	11SEP2013	16:35	15.155	Double Read
					VISIT 3A	09DEC2013	16:35	16.23	Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18	16.43	Single Read
					VISIT 4	22JAN2014	12:50	17.12	Double Read
					VISIT 5	25MAR2014	10:58	15.46	Double Read
					VISIT 6	28MAY2014	13:19	17.195	Double Read
					VISIT 7	30DEC2014	9:25	16.615	Double Read
					VISIT 8	17DEC2015	13:39	15.33	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	VISIT 11	27DEC2018	10:14	15.975	Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31	15.66	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19	6.647035	Double Read
					VISIT 7	30DEC2014	9:25	7.415445	Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	11SEP2013	16:35	10.40315	Double Read
					VISIT 3A	09DEC2013	16:35	11.26765	Double Read
					VISIT 3K	12DEC2013	13:52	12.0666	Single Read
					VISIT 3L	30DEC2013	10:18	11.0319	Single Read
					VISIT 4	22JAN2014	12:50	10.2639	Double Read
					VISIT 5	25MAR2014	10:58	11.348	Double Read
					VISIT 6	28MAY2014	13:19	10.87755	Double Read
					VISIT 7	30DEC2014	9:25	10.71242	Double Read
					VISIT 8	17DEC2015	13:39	10.25595	Double Read
					VISIT 11	27DEC2018	10:14	11.0123	Double Read
					UNSCHEDULED	17DEC2013	12:45	12.2993	Double Read
					UNSCHEDULED	04SEP2015	10:31	11.13735	Double Read
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	11SEP2013	16:35	10.43525	Double Read
					VISIT 3A	09DEC2013	16:35	10.8367	Double Read
					VISIT 3K	12DEC2013	13:52	11.8977	Single Read
					VISIT 3L	30DEC2013	10:18	11.2357	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	VISIT 4	22JAN2014	12:50	11.08615	Double Read
					VISIT 5	25MAR2014	10:58	10.7096	Double Read
					VISIT 6	28MAY2014	13:19	9.691845	Double Read
					VISIT 7	30DEC2014	9:25	10.28372	Double Read
					VISIT 8	17DEC2015	13:39	10.381555	Double Read
					VISIT 11	27DEC2018	10:14	11.83805	Double Read
					UNSCHEDULED	17DEC2013	12:45	11.67175	Double Read
					UNSCHEDULED	04SEP2015	10:31	11.65195	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	N	Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S	4_5	Central Disc		Baseline	11SEP2013	16:35	N	Double Read
					VISIT 3A	09DEC2013	16:35	N	Double Read
					VISIT 3K	12DEC2013	13:52	N	Single Read
					VISIT 3L	30DEC2013	10:18	N	Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	N	Double Read
					VISIT 7	30DEC2014	9:25	N	Double Read
					VISIT 8	17DEC2015	13:39	N	Double Read
					VISIT 11	27DEC2018	10:14	N	Double Read
					UNSCHEDULED	17DEC2013	12:45	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S	4_5	Central Disc		UNSCHEDULED	04SEP2015	10:31	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	11SEP2013	16:35	N	Double Read
					VISIT 3A	09DEC2013	16:35	N	Double Read
					VISIT 3K	12DEC2013	13:52	N	Single Read
					VISIT 3L	30DEC2013	10:18	N	Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	N	Double Read
					VISIT 7	30DEC2014	9:25	N	Double Read
					VISIT 8	17DEC2015	13:39	N	Double Read
					VISIT 11	27DEC2018	10:14	N	Double Read
					UNSCHEDULED	17DEC2013	12:45	N	Double Read
					UNSCHEDULED	04SEP2015	10:31	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	N	Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S	4_5	Central Disc		Baseline	11SEP2013	16:35	N	Double Read
					VISIT 3A	09DEC2013	16:35	N	Double Read
					VISIT 3K	12DEC2013	13:52	N	Single Read
					VISIT 3L	30DEC2013	10:18	N	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S	4_5	Central Disc		VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	N	Double Read
					VISIT 7	30DEC2014	9:25	N	Double Read
					VISIT 8	17DEC2015	13:39	N	Double Read
					VISIT 11	27DEC2018	10:14	N	Double Read
					UNSCHEDULED	17DEC2013	12:45	N	Double Read
					UNSCHEDULED	04SEP2015	10:31	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	11SEP2013	16:35	N	Double Read
					VISIT 3A	09DEC2013	16:35	N	Double Read
					VISIT 3K	12DEC2013	13:52	N	Single Read
					VISIT 3L	30DEC2013	10:18	N	Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	N	Double Read
					VISIT 7	30DEC2014	9:25	N	Double Read
					VISIT 8	17DEC2015	13:39	N	Double Read
					VISIT 11	27DEC2018	10:14	N	Double Read
					UNSCHEDULED	17DEC2013	12:45	N	Double Read
					UNSCHEDULED	04SEP2015	10:31	N	Double Read
Normal lordotic LS	5_S	4_5	General		Baseline	11SEP2013	16:35	N	Double Read
					VISIT 3A	09DEC2013	16:35	Y	Double Read
					VISIT 3K	12DEC2013	13:52	Y	Single Read
					VISIT 3L	30DEC2013	10:18	N	Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	Y	Double Read
					VISIT 6	28MAY2014	13:19	Y	Double Read
					VISIT 7	30DEC2014	9:25	Y	Double Read
					VISIT 8	17DEC2015	13:39	N	Double Read
					VISIT 11	27DEC2018	10:14	Y	Double Read
					UNSCHEDULED	17DEC2013	12:45	N	Double Read
					UNSCHEDULED	04SEP2015	10:31	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50	0	Double Read
					VISIT 5	25MAR2014	10:58	0	Double Read
					VISIT 6	28MAY2014	13:19	0	Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S	4_5	Central Disc		Baseline	11SEP2013	16:35	0	Double Read
					VISIT 3A	09DEC2013	16:35	0	Double Read
					VISIT 3K	12DEC2013	13:52	0	Single Read
					VISIT 3L	30DEC2013	10:18	0	Single Read
					VISIT 4	22JAN2014	12:50	0	Double Read
					VISIT 5	25MAR2014	10:58	0	Double Read
					VISIT 6	28MAY2014	13:19	0	Double Read
					VISIT 7	30DEC2014	9:25	0	Double Read
					VISIT 8	17DEC2015	13:39	1	Double Read
					VISIT 11	27DEC2018	10:14	1	Double Read
					UNSCHEDULED	17DEC2013	12:45	0	Double Read
					UNSCHEDULED	04SEP2015	10:31	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	11SEP2013	16:35	0	Double Read
					VISIT 3A	09DEC2013	16:35	0	Double Read
					VISIT 3K	12DEC2013	13:52	0	Single Read
					VISIT 3L	30DEC2013	10:18	0	Single Read
					VISIT 4	22JAN2014	12:50	0	Double Read
					VISIT 5	25MAR2014	10:58	0	Double Read
					VISIT 6	28MAY2014	13:19	0	Double Read
					VISIT 7	30DEC2014	9:25	0	Double Read
					VISIT 8	17DEC2015	13:39	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 11	27DEC2018	10:14	0	Double Read
					UNSCHEDULED	17DEC2013	12:45	0	Double Read
					UNSCHEDULED	04SEP2015	10:31	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	N	Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
Protruding osteophyte (Central Disc)	5_S	4_5	Central Disc		Baseline	11SEP2013	16:35	N	Double Read
					VISIT 3A	09DEC2013	16:35	N	Double Read
					VISIT 3K	12DEC2013	13:52	N	Single Read
					VISIT 3L	30DEC2013	10:18	N	Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	N	Double Read
					VISIT 7	30DEC2014	9:25	N	Double Read
					VISIT 8	17DEC2015	13:39	N	Double Read
					VISIT 11	27DEC2018	10:14	N	Double Read
					UNSCHEDULED	17DEC2013	12:45	N	Double Read
					UNSCHEDULED	04SEP2015	10:31	N	Double Read
Protruding osteophyte (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	11SEP2013	16:35	N	Double Read
					VISIT 3A	09DEC2013	16:35	N	Double Read
					VISIT 3K	12DEC2013	13:52	N	Single Read
					VISIT 3L	30DEC2013	10:18	N	Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 6	28MAY2014	13:19	N	Double Read
					VISIT 7	30DEC2014	9:25	N	Double Read
					VISIT 8	17DEC2015	13:39	N	Double Read
					VISIT 11	27DEC2018	10:14	N	Double Read
					UNSCHEDULED	17DEC2013	12:45	N	Double Read
					UNSCHEDULED	04SEP2015	10:31	N	Double Read
Relevant scoliosis	5_S	4_5	General		Baseline	11SEP2013	16:35	N	Double Read
					VISIT 3A	09DEC2013	16:35	N	Double Read
					VISIT 3K	12DEC2013	13:52	N	Single Read
					VISIT 3L	30DEC2013	10:18	N	Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	N	Double Read
					VISIT 7	30DEC2014	9:25	N	Double Read
					VISIT 8	17DEC2015	13:39	N	Double Read
					VISIT 11	27DEC2018	10:14	N	Double Read
					UNSCHEDULED	17DEC2013	12:45	N	Double Read
					UNSCHEDULED	04SEP2015	10:31	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	N	Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S	4_5	Central Disc		Baseline	11SEP2013	16:35	N	Double Read
					VISIT 3A	09DEC2013	16:35	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S	4_5	Central Disc		VISIT 3K	12DEC2013	13:52	N	Single Read
					VISIT 3L	30DEC2013	10:18	N	Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	N	Double Read
					VISIT 7	30DEC2014	9:25	N	Double Read
					VISIT 8	17DEC2015	13:39	N	Double Read
					VISIT 11	27DEC2018	10:14	N	Double Read
					UNSCHEDULED	17DEC2013	12:45	N	Double Read
					UNSCHEDULED	04SEP2015	10:31	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	11SEP2013	16:35	N	Double Read
					VISIT 3A	09DEC2013	16:35	N	Double Read
					VISIT 3K	12DEC2013	13:52	N	Single Read
					VISIT 3L	30DEC2013	10:18	N	Single Read
					VISIT 4	22JAN2014	12:50	N	Double Read
					VISIT 5	25MAR2014	10:58	N	Double Read
					VISIT 6	28MAY2014	13:19	N	Double Read
					VISIT 7	30DEC2014	9:25	N	Double Read
					VISIT 8	17DEC2015	13:39	N	Double Read
					VISIT 11	27DEC2018	10:14	N	Double Read
					UNSCHEDULED	17DEC2013	12:45	N	Double Read
					UNSCHEDULED	04SEP2015	10:31	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	UNSCHEDULED	04SEP2015	10:31		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19	95.08688	Double Read
					VISIT 7	30DEC2014	9:25	76.35152	Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18	115.5216	Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	11SEP2013	16:35	85.25408	Double Read
					VISIT 3A	09DEC2013	16:35	78.86784	Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18	88.37696	Single Read
					VISIT 4	22JAN2014	12:50	85.05824	Double Read
					VISIT 5	25MAR2014	10:58	84.76768	Double Read
					VISIT 6	28MAY2014	13:19	88.77104	Double Read
					VISIT 7	30DEC2014	9:25	69.00384	Double Read
					VISIT 8	17DEC2015	13:39	76.55888	Double Read
					VISIT 11	27DEC2018	10:14	86.14512	Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31	68.9888	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18	83.504	Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2 (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	11SEP2013	16:35		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
T2 (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	11SEP2013	16:35	79.54576	Double Read
					VISIT 3A	09DEC2013	16:35	81.16096	Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18	91.35456	Single Read
					VISIT 4	22JAN2014	12:50	82.8688	Double Read
					VISIT 5	25MAR2014	10:58	85.87968	Double Read
					VISIT 6	28MAY2014	13:19	84.49408	Double Read
					VISIT 7	30DEC2014	9:25	74.70544	Double Read
					VISIT 8	17DEC2015	13:39	81.67152	Double Read
					VISIT 11	27DEC2018	10:14	70.97568	Double Read
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S	4_5	Central Disc		Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52	equal	Single Read
					VISIT 3L	30DEC2013	10:18	equal	Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		VISIT 3K	12DEC2013	13:52	equal	Single Read
					VISIT 3L	30DEC2013	10:18	equal	Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19	equal	Double Read
					VISIT 7	30DEC2014	9:25	equal	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52	lower	Single Read
					VISIT 3L	30DEC2013	10:18	lower	Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25	equal	Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	11SEP2013	16:35	higher	Double Read
					VISIT 3A	09DEC2013	16:35	higher	Double Read
					VISIT 3K	12DEC2013	13:52	higher	Single Read
					VISIT 3L	30DEC2013	10:18	higher	Single Read
					VISIT 4	22JAN2014	12:50	higher	Double Read
					VISIT 5	25MAR2014	10:58	equal	Double Read
					VISIT 6	28MAY2014	13:19	higher	Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39	higher	Double Read
					VISIT 11	27DEC2018	10:14	higher	Double Read
					UNSCHEDULED	17DEC2013	12:45	higher	Double Read
					UNSCHEDULED	04SEP2015	10:31	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	11SEP2013	16:35	equal	Double Read
					VISIT 3A	09DEC2013	16:35	lower	Double Read
					VISIT 3K	12DEC2013	13:52	lower	Single Read
					VISIT 3L	30DEC2013	10:18	lower	Single Read
					VISIT 4	22JAN2014	12:50	equal	Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19	equal	Double Read
					VISIT 7	30DEC2014	9:25	equal	Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14	equal	Double Read
					UNSCHEDULED	17DEC2013	12:45	equal	Double Read
					UNSCHEDULED	04SEP2015	10:31	equal	Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S	4_5	Caudal Disc		VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S	4_5	Central Disc		Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52	equal	Single Read
					VISIT 3L	30DEC2013	10:18	equal	Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52	equal	Single Read
					VISIT 3L	30DEC2013	10:18	equal	Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	11SEP2013	16:35		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19	18.7713266519	Double Read
					VISIT 7	30DEC2014	9:25	3.73299813148	Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18	23.708782062	Single Read
								2	
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	11SEP2013	16:35	16.816320706	Double Read
					VISIT 3A	09DEC2013	16:35	13.325456089	Double Read
								7	
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18	9.7845150331	Single Read
								2	
					VISIT 4	22JAN2014	12:50	15.619568540	Double Read
								9	
					VISIT 5	25MAR2014	10:58	15.640903686	Double Read
					VISIT 6	28MAY2014	13:19	14.373772719	Double Read
			6						
	VISIT 7	30DEC2014	9:25	8.3887548836	Double Read				
			4						
	VISIT 8	17DEC2015	13:39	3.5617666043	Double Read				
			8						

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	VISIT 11	27DEC2018	10:14	18.4324783421	Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31	9.8321386105	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18	8.46158654663	Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	11SEP2013	16:35	14.367392559	Double Read
					VISIT 3A	09DEC2013	16:35	12.903760829	Double Read
					VISIT 3K	12DEC2013	13:52		Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	VISIT 3L	30DEC2013	10:18	17.9614744352	Single Read
					VISIT 4	22JAN2014	12:50	12.3596806523	Double Read
					VISIT 5	25MAR2014	10:58	16.9626634958	Double Read
					VISIT 6	28MAY2014	13:19	17.0883641923	Double Read
					VISIT 7	30DEC2014	9:25	8.9689145575	Double Read
					VISIT 8	17DEC2015	13:39	11.1648989299	Double Read
					VISIT 11	27DEC2018	10:14	13.1929131986	Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31	8.2066995074	Double Read
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
Volume (mm ³) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
Volume (mm ³) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
Volume (mm ³) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	11SEP2013	16:35	22544.5	Double Read
					VISIT 3A	09DEC2013	16:35	23861.5	Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50	23731.0	Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14	20647.5	Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18	6612	Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	UNSCHEDULED	04SEP2015	10:31		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	11SEP2013	16:35	23890.0	Double Read
					VISIT 3A	09DEC2013	16:35	24743.0	Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50	25025.5	Double Read
					VISIT 5	25MAR2014	10:58		Double Read
					VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14	23672.5	Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	11SEP2013	16:35		Double Read
					VISIT 3A	09DEC2013	16:35		Double Read
					VISIT 3K	12DEC2013	13:52		Single Read
					VISIT 3L	30DEC2013	10:18		Single Read
					VISIT 4	22JAN2014	12:50		Double Read
					VISIT 5	25MAR2014	10:58		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0208 Age=45 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	VISIT 6	28MAY2014	13:19		Double Read
					VISIT 7	30DEC2014	9:25		Double Read
					VISIT 8	17DEC2015	13:39		Double Read
					VISIT 11	27DEC2018	10:14		Double Read
					UNSCHEDULED	17DEC2013	12:45		Double Read
					UNSCHEDULED	04SEP2015	10:31		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	22OCT2014	15:22	3	Double Read
					VISIT 3A	29JAN2015	14:50	3	Double Read
					VISIT 4	24MAR2015	13:39	3	Double Read
					VISIT 6	16JUL2015	12:28	2	Double Read
					VISIT 7	23FEB2016	12:24	2	Double Read
					VISIT 8	19JAN2017	14:41	2	Double Read
					VISIT 11	30DEC2019	10:05	3	Double Read
					UNSCHEDULED	05NOV2015	8:44	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	22OCT2014	15:22	3	Double Read
					VISIT 3A	29JAN2015	14:50	3	Double Read
					VISIT 4	24MAR2015	13:39	3	Double Read
					VISIT 6	16JUL2015	12:28	4	Double Read
					VISIT 7	23FEB2016	12:24	4	Double Read
					VISIT 8	19JAN2017	14:41	4	Double Read
					VISIT 11	30DEC2019	10:05	4	Double Read
					UNSCHEDULED	05NOV2015	8:44	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	22OCT2014	15:22	2	Double Read
					VISIT 3A	29JAN2015	14:50	2	Double Read
					VISIT 4	24MAR2015	13:39	1	Double Read
					VISIT 6	16JUL2015	12:28	2	Double Read
					VISIT 7	23FEB2016	12:24	2	Double Read
					VISIT 8	19JAN2017	14:41	1	Double Read
					VISIT 11	30DEC2019	10:05	2	Double Read
					UNSCHEDULED	05NOV2015	8:44	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	22OCT2014	15:22	N	Double Read
					VISIT 3A	29JAN2015	14:50	N	Double Read
					VISIT 4	24MAR2015	13:39	N	Double Read
					VISIT 6	16JUL2015	12:28	N	Double Read
					VISIT 7	23FEB2016	12:24	N	Double Read
					VISIT 8	19JAN2017	14:41	N	Double Read
					VISIT 11	30DEC2019	10:05	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		UNSCHEDULED	05NOV2015	8:44	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	22OCT2014	15:22	N	Double Read
					VISIT 3A	29JAN2015	14:50	N	Double Read
					VISIT 4	24MAR2015	13:39	N	Double Read
					VISIT 6	16JUL2015	12:28	N	Double Read
					VISIT 7	23FEB2016	12:24	N	Double Read
					VISIT 8	19JAN2017	14:41	N	Double Read
					VISIT 11	30DEC2019	10:05	N	Double Read
					UNSCHEDULED	05NOV2015	8:44	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	22OCT2014	15:22	N	Double Read
					VISIT 3A	29JAN2015	14:50	N	Double Read
					VISIT 4	24MAR2015	13:39	N	Double Read
					VISIT 6	16JUL2015	12:28	N	Double Read
					VISIT 7	23FEB2016	12:24	N	Double Read
					VISIT 8	19JAN2017	14:41	N	Double Read
					VISIT 11	30DEC2019	10:05	N	Double Read
					UNSCHEDULED	05NOV2015	8:44	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	22OCT2014	15:22	N	Double Read
					VISIT 3A	29JAN2015	14:50	N	Double Read
					VISIT 4	24MAR2015	13:39	N	Double Read
					VISIT 6	16JUL2015	12:28	N	Double Read
					VISIT 7	23FEB2016	12:24	N	Double Read
					VISIT 8	19JAN2017	14:41	N	Double Read
					VISIT 11	30DEC2019	10:05	N	Double Read
					UNSCHEDULED	05NOV2015	8:44	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	22OCT2014	15:22	Y	Double Read
					VISIT 3A	29JAN2015	14:50	Y	Double Read
					VISIT 4	24MAR2015	13:39	Y	Double Read
					VISIT 6	16JUL2015	12:28	Y	Double Read
					VISIT 7	23FEB2016	12:24	Y	Double Read
					VISIT 8	19JAN2017	14:41	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		VISIT 11	30DEC2019	10:05	Y	Double Read
					UNSCHEDULED	05NOV2015	8:44	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	22OCT2014	15:22	N	Double Read
					VISIT 3A	29JAN2015	14:50	N	Double Read
					VISIT 4	24MAR2015	13:39	N	Double Read
					VISIT 6	16JUL2015	12:28	N	Double Read
					VISIT 7	23FEB2016	12:24	N	Double Read
					VISIT 8	19JAN2017	14:41	N	Double Read
					VISIT 11	30DEC2019	10:05	N	Double Read
					UNSCHEDULED	05NOV2015	8:44	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	22OCT2014	15:22	N	Double Read
					VISIT 3A	29JAN2015	14:50	N	Double Read
					VISIT 4	24MAR2015	13:39	N	Double Read
					VISIT 6	16JUL2015	12:28	N	Double Read
					VISIT 7	23FEB2016	12:24	N	Double Read
					VISIT 8	19JAN2017	14:41	N	Double Read
					VISIT 11	30DEC2019	10:05	N	Double Read
					UNSCHEDULED	05NOV2015	8:44	N	Double Read
Fracture	4_5		General		Baseline	22OCT2014	15:22	N	Double Read
					VISIT 3A	29JAN2015	14:50	N	Double Read
					VISIT 4	24MAR2015	13:39	N	Double Read
					VISIT 6	16JUL2015	12:28	N	Double Read
					VISIT 7	23FEB2016	12:24	N	Double Read
					VISIT 8	19JAN2017	14:41	N	Double Read
					VISIT 11	30DEC2019	10:05	N	Double Read
					UNSCHEDULED	05NOV2015	8:44	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	22OCT2014	15:22	12.68	Double Read
					VISIT 3A	29JAN2015	14:50	13.055	Double Read
					VISIT 4	24MAR2015	13:39	13.275	Double Read
					VISIT 6	16JUL2015	12:28	13.385	Double Read
					VISIT 7	23FEB2016	12:24	13.175	Double Read
					VISIT 8	19JAN2017	14:41	13.325	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	VISIT 11	30DEC2019	10:05	13.72	Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	22OCT2014	15:22	9.115	Double Read
					VISIT 3A	29JAN2015	14:50	8.77	Double Read
					VISIT 4	24MAR2015	13:39	7.745	Double Read
					VISIT 6	16JUL2015	12:28	8.935	Double Read
					VISIT 7	23FEB2016	12:24	9.435	Double Read
					VISIT 8	19JAN2017	14:41	9.38	Double Read
					VISIT 11	30DEC2019	10:05	9.805	Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	22OCT2014	15:22	10.3	Double Read
					VISIT 3A	29JAN2015	14:50	11.47	Double Read
					VISIT 4	24MAR2015	13:39	11.03	Double Read
					VISIT 6	16JUL2015	12:28	10.73	Double Read
					VISIT 7	23FEB2016	12:24	11.225	Double Read
					VISIT 8	19JAN2017	14:41	10.795	Double Read
					VISIT 11	30DEC2019	10:05	11.665	Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	22OCT2014	15:22	8.69738	Double Read
					VISIT 3A	29JAN2015	14:50	9.28754	Double Read
					VISIT 4	24MAR2015	13:39	8.61771	Double Read
					VISIT 6	16JUL2015	12:28	9.92519	Double Read
					VISIT 7	23FEB2016	12:24	9.00184	Double Read
					VISIT 8	19JAN2017	14:41	9.635275	Double Read
					VISIT 11	30DEC2019	10:05	9.351285	Double Read
					UNSCHEDULED	05NOV2015	8:44	9.6712	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	22OCT2014	15:22	7.80251	Double Read
					VISIT 3A	29JAN2015	14:50	5.82901	Double Read
					VISIT 4	24MAR2015	13:39	5.765365	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 6	16JUL2015	12:28	7.525445	Double Read
					VISIT 7	23FEB2016	12:24	7.46874	Double Read
					VISIT 8	19JAN2017	14:41	7.140295	Double Read
					VISIT 11	30DEC2019	10:05	7.977005	Double Read
					UNSCHEDULED	05NOV2015	8:44	7.18686	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	22OCT2014	15:22	8.942955	Double Read
					VISIT 3A	29JAN2015	14:50	9.87971	Double Read
					VISIT 4	24MAR2015	13:39	8.8593	Double Read
					VISIT 6	16JUL2015	12:28	10.30605	Double Read
					VISIT 7	23FEB2016	12:24	8.537715	Double Read
					VISIT 8	19JAN2017	14:41	9.522485	Double Read
					VISIT 11	30DEC2019	10:05	9.48591	Double Read
					UNSCHEDULED	05NOV2015	8:44	9.55353	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	22OCT2014	15:22	N	Double Read
					VISIT 3A	29JAN2015	14:50	N	Double Read
					VISIT 4	24MAR2015	13:39	N	Double Read
					VISIT 6	16JUL2015	12:28	N	Double Read
					VISIT 7	23FEB2016	12:24	N	Double Read
					VISIT 8	19JAN2017	14:41	N	Double Read
					VISIT 11	30DEC2019	10:05	N	Double Read
					UNSCHEDULED	05NOV2015	8:44	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	22OCT2014	15:22	N	Double Read
					VISIT 3A	29JAN2015	14:50	N	Double Read
					VISIT 4	24MAR2015	13:39	N	Double Read
					VISIT 6	16JUL2015	12:28	N	Double Read
					VISIT 7	23FEB2016	12:24	N	Double Read
					VISIT 8	19JAN2017	14:41	N	Double Read
					VISIT 11	30DEC2019	10:05	N	Double Read
					UNSCHEDULED	05NOV2015	8:44	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	22OCT2014	15:22	N	Double Read
					VISIT 3A	29JAN2015	14:50	N	Double Read
					VISIT 4	24MAR2015	13:39	N	Double Read
					VISIT 6	16JUL2015	12:28	N	Double Read
					VISIT 7	23FEB2016	12:24	N	Double Read
					VISIT 8	19JAN2017	14:41	N	Double Read
					VISIT 11	30DEC2019	10:05	N	Double Read
					UNSCHEDULED	05NOV2015	8:44	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	22OCT2014	15:22	N	Double Read
					VISIT 3A	29JAN2015	14:50	N	Double Read
					VISIT 4	24MAR2015	13:39	N	Double Read
					VISIT 6	16JUL2015	12:28	N	Double Read
					VISIT 7	23FEB2016	12:24	N	Double Read
					VISIT 8	19JAN2017	14:41	N	Double Read
					VISIT 11	30DEC2019	10:05	N	Double Read
					UNSCHEDULED	05NOV2015	8:44	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	22OCT2014	15:22	N	Double Read
					VISIT 3A	29JAN2015	14:50	N	Double Read
					VISIT 4	24MAR2015	13:39	N	Double Read
					VISIT 6	16JUL2015	12:28	N	Double Read
					VISIT 7	23FEB2016	12:24	N	Double Read
					VISIT 8	19JAN2017	14:41	N	Double Read
					VISIT 11	30DEC2019	10:05	N	Double Read
					UNSCHEDULED	05NOV2015	8:44	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	22OCT2014	15:22	N	Double Read
					VISIT 3A	29JAN2015	14:50	N	Double Read
					VISIT 4	24MAR2015	13:39	N	Double Read
					VISIT 6	16JUL2015	12:28	N	Double Read
					VISIT 7	23FEB2016	12:24	N	Double Read
					VISIT 8	19JAN2017	14:41	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 11	30DEC2019	10:05	N	Double Read
					UNSCHEDULED	05NOV2015	8:44	N	Double Read
Normal lordotic LS	4_5		General		Baseline	22OCT2014	15:22	Y	Double Read
					VISIT 3A	29JAN2015	14:50	Y	Double Read
					VISIT 4	24MAR2015	13:39	Y	Double Read
					VISIT 6	16JUL2015	12:28	Y	Double Read
					VISIT 7	23FEB2016	12:24	Y	Double Read
					VISIT 8	19JAN2017	14:41	Y	Double Read
					VISIT 11	30DEC2019	10:05	Y	Double Read
					UNSCHEDULED	05NOV2015	8:44	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	22OCT2014	15:22	0	Double Read
					VISIT 3A	29JAN2015	14:50	0	Double Read
					VISIT 4	24MAR2015	13:39	0	Double Read
					VISIT 6	16JUL2015	12:28	0	Double Read
					VISIT 7	23FEB2016	12:24	0	Double Read
					VISIT 8	19JAN2017	14:41	0	Double Read
					VISIT 11	30DEC2019	10:05	0	Double Read
					UNSCHEDULED	05NOV2015	8:44	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	22OCT2014	15:22	0	Double Read
					VISIT 3A	29JAN2015	14:50	0	Double Read
					VISIT 4	24MAR2015	13:39	0	Double Read
					VISIT 6	16JUL2015	12:28	0	Double Read
					VISIT 7	23FEB2016	12:24	0	Double Read
					VISIT 8	19JAN2017	14:41	0	Double Read
					VISIT 11	30DEC2019	10:05	0	Double Read
					UNSCHEDULED	05NOV2015	8:44	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	22OCT2014	15:22	0	Double Read
					VISIT 3A	29JAN2015	14:50	0	Double Read
					VISIT 4	24MAR2015	13:39	0	Double Read
					VISIT 6	16JUL2015	12:28	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	23FEB2016	12:24	0	Double Read
					VISIT 8	19JAN2017	14:41	0	Double Read
					VISIT 11	30DEC2019	10:05	0	Double Read
					UNSCHEDULED	05NOV2015	8:44	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	22OCT2014	15:22	N	Double Read
					VISIT 3A	29JAN2015	14:50	N	Double Read
					VISIT 4	24MAR2015	13:39	N	Double Read
					VISIT 6	16JUL2015	12:28	N	Double Read
					VISIT 7	23FEB2016	12:24	N	Double Read
					VISIT 8	19JAN2017	14:41	N	Double Read
					VISIT 11	30DEC2019	10:05	N	Double Read
					UNSCHEDULED	05NOV2015	8:44	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	22OCT2014	15:22	N	Double Read
					VISIT 3A	29JAN2015	14:50	N	Double Read
					VISIT 4	24MAR2015	13:39	N	Double Read
					VISIT 6	16JUL2015	12:28	N	Double Read
					VISIT 7	23FEB2016	12:24	N	Double Read
					VISIT 8	19JAN2017	14:41	N	Double Read
					VISIT 11	30DEC2019	10:05	N	Double Read
					UNSCHEDULED	05NOV2015	8:44	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	22OCT2014	15:22	N	Double Read
					VISIT 3A	29JAN2015	14:50	N	Double Read
					VISIT 4	24MAR2015	13:39	N	Double Read
					VISIT 6	16JUL2015	12:28	N	Double Read
					VISIT 7	23FEB2016	12:24	N	Double Read
					VISIT 8	19JAN2017	14:41	N	Double Read
					VISIT 11	30DEC2019	10:05	N	Double Read
					UNSCHEDULED	05NOV2015	8:44	N	Double Read
Relevant scoliosis	4_5		General		Baseline	22OCT2014	15:22	N	Double Read
					VISIT 3A	29JAN2015	14:50	N	Double Read
					VISIT 4	24MAR2015	13:39	N	Double Read
					VISIT 6	16JUL2015	12:28	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Relevant scoliosis	4_5		General		VISIT 7 VISIT 8 VISIT 11 UNSCHEDULED	23FEB2016 19JAN2017 30DEC2019 05NOV2015	12:24 14:41 10:05 8:44	N N N N	Double Read Double Read Double Read Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline VISIT 3A VISIT 4 VISIT 6 VISIT 7 VISIT 8 VISIT 11 UNSCHEDULED	22OCT2014 29JAN2015 24MAR2015 16JUL2015 23FEB2016 19JAN2017 30DEC2019 05NOV2015	15:22 14:50 13:39 12:28 12:24 14:41 10:05 8:44	N N N N N N N N	Double Read Double Read Double Read Double Read Double Read Double Read Double Read Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline VISIT 3A VISIT 4 VISIT 6 VISIT 7 VISIT 8 VISIT 11 UNSCHEDULED	22OCT2014 29JAN2015 24MAR2015 16JUL2015 23FEB2016 19JAN2017 30DEC2019 05NOV2015	15:22 14:50 13:39 12:28 12:24 14:41 10:05 8:44	N N N N N N N N	Double Read Double Read Double Read Double Read Double Read Double Read Double Read Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline VISIT 3A VISIT 4 VISIT 6 VISIT 7 VISIT 8 VISIT 11 UNSCHEDULED	22OCT2014 29JAN2015 24MAR2015 16JUL2015 23FEB2016 19JAN2017 30DEC2019 05NOV2015	15:22 14:50 13:39 12:28 12:24 14:41 10:05 8:44	N N N N N N N N	Double Read Double Read Double Read Double Read Double Read Double Read Double Read Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline VISIT 3A	22OCT2014 29JAN2015	15:22 14:50		Double Read Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	22OCT2014	15:22	81.09248	Double Read
					VISIT 3A	29JAN2015	14:50	80.34144	Double Read
					VISIT 4	24MAR2015	13:39	75.0592	Double Read
					VISIT 6	16JUL2015	12:28	94.85072	Double Read
					VISIT 7	23FEB2016	12:24	76.63984	Double Read
					VISIT 8	19JAN2017	14:41	84.43664	Double Read
					VISIT 11	30DEC2019	10:05	82.9896	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	22OCT2014	15:22	78.12816	Double Read
					VISIT 3A	29JAN2015	14:50	69.59952	Double Read
					VISIT 4	24MAR2015	13:39	61.16064	Double Read
					VISIT 6	16JUL2015	12:28	95.7104	Double Read
					VISIT 7	23FEB2016	12:24	77.47264	Double Read
					VISIT 8	19JAN2017	14:41	97.06496	Double Read
					VISIT 11	30DEC2019	10:05	79.69008	Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	22OCT2014	15:22	100.7848	Double Read
					VISIT 3A	29JAN2015	14:50	103.5984	Double Read
					VISIT 4	24MAR2015	13:39	90.852	Double Read
					VISIT 6	16JUL2015	12:28	114.20544	Double Read
					VISIT 7	23FEB2016	12:24	99.00432	Double Read
					VISIT 8	19JAN2017	14:41	100.5408	Double Read
					VISIT 11	30DEC2019	10:05	112.59488	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	UNSCHEDULED	05NOV2015	8:44		Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	22OCT2014	15:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	22OCT2014	15:22	lower	Double Read
					VISIT 3A	29JAN2015	14:50	lower	Double Read
					VISIT 4	24MAR2015	13:39	lower	Double Read
					VISIT 6	16JUL2015	12:28	lower	Double Read
					VISIT 7	23FEB2016	12:24	lower	Double Read
					VISIT 8	19JAN2017	14:41	lower	Double Read
					VISIT 11	30DEC2019	10:05	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	22OCT2014	15:22	lower	Double Read
					VISIT 3A	29JAN2015	14:50	lower	Double Read
					VISIT 4	24MAR2015	13:39	lower	Double Read
					VISIT 6	16JUL2015	12:28	lower	Double Read
					VISIT 7	23FEB2016	12:24	lower	Double Read
					VISIT 8	19JAN2017	14:41	lower	Double Read
					VISIT 11	30DEC2019	10:05	lower	Double Read
					UNSCHEDULED	05NOV2015	8:44	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 11	30DEC2019	10:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		UNSCHEDULED	05NOV2015	8:44		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	22OCT2014	15:22	5.90761338542	Double Read
					VISIT 3A	29JAN2015	14:50	9.97112281299	Double Read
					VISIT 4	24MAR2015	13:39	3.08060472227	Double Read
					VISIT 6	16JUL2015	12:28	4.74680482419	Double Read
					VISIT 7	23FEB2016	12:24	10.2768812638	Double Read
					VISIT 8	19JAN2017	14:41	14.4984542212	Double Read
					VISIT 11	30DEC2019	10:05	9.23079327332	Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	22OCT2014	15:22	3.2727501273	Double Read
					VISIT 3A	29JAN2015	14:50	5.9490810259	Double Read
					VISIT 4	24MAR2015	13:39	5.3790793273	Double Read
					VISIT 6	16JUL2015	12:28	5.6055715984	Double Read
					VISIT 7	23FEB2016	12:24	15.910786478	Double Read
					VISIT 8	19JAN2017	14:41	13.429203329	Double Read
					VISIT 11	30DEC2019	10:05	6.1095022931	Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	22OCT2014	15:22	1.9393035502	Double Read
					VISIT 3A	29JAN2015	14:50	3.47819942246	Double Read
					VISIT 4	24MAR2015	13:39	9.48417190421	Double Read
					VISIT 6	16JUL2015	12:28	1.66064888738	Double Read
					VISIT 7	23FEB2016	12:24	4.6193239341	Double Read
					VISIT 8	19JAN2017	14:41	20.2415491762	Double Read
					VISIT 11	30DEC2019	10:05	4.3032648208	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	UNSCHEDULED	05NOV2015	8:44		Double Read
					Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
					Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	UNSCHEDULED	05NOV2015	8:44		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	22OCT2014	15:22	11208.0	Double Read
					VISIT 3A	29JAN2015	14:50	11108.5	Double Read
					VISIT 4	24MAR2015	13:39	11396.0	Double Read
					VISIT 6	16JUL2015	12:28	12170.0	Double Read
					VISIT 7	23FEB2016	12:24	11852.5	Double Read
					VISIT 8	19JAN2017	14:41	12214.5	Double Read
					VISIT 11	30DEC2019	10:05	11755.5	Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	22OCT2014	15:22	9255.5	Double Read
					VISIT 3A	29JAN2015	14:50	8953.0	Double Read
					VISIT 4	24MAR2015	13:39	8354.5	Double Read
					VISIT 6	16JUL2015	12:28	9235.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 7	23FEB2016	12:24	8769.0	Double Read
					VISIT 8	19JAN2017	14:41	10936.5	Double Read
					VISIT 11	30DEC2019	10:05	9332.5	Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22OCT2014	15:22		Double Read
					VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	22OCT2014	15:22	10670.5	Double Read
					VISIT 3A	29JAN2015	14:50	12026.0	Double Read
					VISIT 4	24MAR2015	13:39	11241.0	Double Read
					VISIT 6	16JUL2015	12:28	11104.5	Double Read
					VISIT 7	23FEB2016	12:24	12149.0	Double Read
					VISIT 8	19JAN2017	14:41	12723.5	Double Read
					VISIT 11	30DEC2019	10:05	11859.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	22OCT2014	15:22		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0209 Age=25 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 3A	29JAN2015	14:50		Double Read
					VISIT 4	24MAR2015	13:39		Double Read
					VISIT 6	16JUL2015	12:28		Double Read
					VISIT 7	23FEB2016	12:24		Double Read
					VISIT 8	19JAN2017	14:41		Double Read
					VISIT 11	30DEC2019	10:05		Double Read
					UNSCHEDULED	05NOV2015	8:44		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0210 Age=32 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	12NOV2014	19:37	4	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	12NOV2014	19:37	2	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	12NOV2014	19:37	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	12NOV2014	19:37	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	12NOV2014	19:37	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	12NOV2014	19:37	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	12NOV2014	19:37	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	12NOV2014	19:37	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	12NOV2014	19:37	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	12NOV2014	19:37	N	Double Read
Fracture	4_5		General		Baseline	12NOV2014	19:37	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	12NOV2014	19:37	16.42	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	12NOV2014	19:37	12.78	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	12NOV2014	19:37	12.38	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0210 Age=32 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	12NOV2014	19:37	12.05015	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	12NOV2014	19:37	10.492045	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	12NOV2014	19:37	9.54904	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	12NOV2014	19:37	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	12NOV2014	19:37	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	12NOV2014	19:37	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	12NOV2014	19:37	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	12NOV2014	19:37	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	12NOV2014	19:37	N	Double Read
Normal lordotic LS	4_5		General		Baseline	12NOV2014	19:37	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	12NOV2014	19:37	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	12NOV2014	19:37	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0210 Age=32 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	12NOV2014	19:37	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	12NOV2014	19:37	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	12NOV2014	19:37	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	12NOV2014	19:37	N	Double Read
Relevant scoliosis	4_5		General		Baseline	12NOV2014	19:37	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	12NOV2014	19:37	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	12NOV2014	19:37	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	12NOV2014	19:37	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	12NOV2014	19:37		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	12NOV2014	19:37	58.81248	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	12NOV2014	19:37		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	12NOV2014	19:37		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	12NOV2014	19:37	69.37792	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	12NOV2014	19:37		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0210 Age=32 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	12NOV2014	19:37		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	12NOV2014	19:37	68.0096	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	12NOV2014	19:37		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	12NOV2014	19:37		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	12NOV2014	19:37		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	12NOV2014	19:37		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	12NOV2014	19:37		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	12NOV2014	19:37	higher	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	12NOV2014	19:37		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	12NOV2014	19:37		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0210 Age=32 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	12NOV2014	19:37	higher	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	12NOV2014	19:37		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	12NOV2014	19:37		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	12NOV2014	19:37		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	12NOV2014	19:37		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	12NOV2014	19:37		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	12NOV2014	19:37	9.73169356209	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	12NOV2014	19:37		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	12NOV2014	19:37		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	12NOV2014	19:37	6.55289960931	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	12NOV2014	19:37		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	12NOV2014	19:37		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0210 Age=32 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	12NOV2014	19:37	14.1206726686	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	12NOV2014	19:37		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	12NOV2014	19:37		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	12NOV2014	19:37	14621.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	12NOV2014	19:37		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	12NOV2014	19:37		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	12NOV2014	19:37	14832.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	12NOV2014	19:37		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	12NOV2014	19:37		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	12NOV2014	19:37	15040.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	12NOV2014	19:37		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0211 Age=28 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	10DEC2014	16:45	3	Double Read
					VISIT 3A	04MAR2015	16:02	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	10DEC2014	16:45	2	Double Read
					VISIT 3A	04MAR2015	16:02	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	10DEC2014	16:45	N	Double Read
					VISIT 3A	04MAR2015	16:02	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	10DEC2014	16:45	N	Double Read
					VISIT 3A	04MAR2015	16:02	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	10DEC2014	16:45	Y	Double Read
					VISIT 3A	04MAR2015	16:02	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	10DEC2014	16:45	N	Double Read
					VISIT 3A	04MAR2015	16:02	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	10DEC2014	16:45	N	Double Read
					VISIT 3A	04MAR2015	16:02	N	Double Read
Fracture	5_S		General		Baseline	10DEC2014	16:45	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0211 Age=28 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Fracture	5_S		General		VISIT 3A	04MAR2015	16:02	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	10DEC2014	16:45	14.055	Double Read
					VISIT 3A	04MAR2015	16:02	15.35	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	10DEC2014	16:45	12.715	Double Read
					VISIT 3A	04MAR2015	16:02	13.635	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	10DEC2014	16:45	8.675485	Double Read
					VISIT 3A	04MAR2015	16:02	7.89606	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	10DEC2014	16:45	10.86255	Double Read
					VISIT 3A	04MAR2015	16:02	11.3296	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	10DEC2014	16:45	N	Double Read
					VISIT 3A	04MAR2015	16:02	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0211 Age=28 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	10DEC2014	16:45	N	Double Read
					VISIT 3A	04MAR2015	16:02	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	10DEC2014	16:45	N	Double Read
					VISIT 3A	04MAR2015	16:02	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	10DEC2014	16:45	N	Double Read
					VISIT 3A	04MAR2015	16:02	N	Double Read
Normal lordotic LS	5_S		General		Baseline	10DEC2014	16:45	N	Double Read
					VISIT 3A	04MAR2015	16:02	N	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	10DEC2014	16:45	0	Double Read
					VISIT 3A	04MAR2015	16:02	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	10DEC2014	16:45	0	Double Read
					VISIT 3A	04MAR2015	16:02	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	10DEC2014	16:45	N	Double Read
					VISIT 3A	04MAR2015	16:02	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0211 Age=28 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	10DEC2014	16:45	N	Double Read
					VISIT 3A	04MAR2015	16:02	N	Double Read
Relevant scoliosis	5_S		General		Baseline	10DEC2014	16:45	N	Double Read
					VISIT 3A	04MAR2015	16:02	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	10DEC2014	16:45	N	Double Read
					VISIT 3A	04MAR2015	16:02	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	10DEC2014	16:45	N	Double Read
					VISIT 3A	04MAR2015	16:02	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	10DEC2014	16:45	66.40608	Double Read
					VISIT 3A	04MAR2015	16:02	71.44432	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0211 Age=28 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	10DEC2014	16:45	112.31488	Double Read
					VISIT 3A	04MAR2015	16:02	108.58048	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0211 Age=28 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	10DEC2014	16:45	lower	Double Read
					VISIT 3A	04MAR2015	16:02	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0211 Age=28 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	10DEC2014	16:45	10.1393647019	Double Read
					VISIT 3A	04MAR2015	16:02	10.7015457788	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	10DEC2014	16:45	5.0959741804	Double Read
					VISIT 3A	04MAR2015	16:02	3.35484966877	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0211 Age=28 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	10DEC2014	16:45	15884.0	Double Read
					VISIT 3A	04MAR2015	16:02	16146.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	10DEC2014	16:45	15959.5	Double Read
					VISIT 3A	04MAR2015	16:02	17807.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	10DEC2014	16:45		Double Read
					VISIT 3A	04MAR2015	16:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0212 Age=36 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	3_4		Caudal Disc		Baseline	15DEC2014	15:38	3	Double Read
					VISIT 4	30JAN2015	7:40	3	Double Read
					VISIT 6	25JUN2015	13:35	3	Double Read
					VISIT 7	28JAN2016	7:42	3	Double Read
					VISIT 8	28DEC2016	12:07	3	Double Read
					VISIT 11	27DEC2019	11:04	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	3_4		Central Disc		Baseline	15DEC2014	15:38	3	Double Read
					VISIT 4	30JAN2015	7:40	3	Double Read
					VISIT 6	25JUN2015	13:35	3	Double Read
					VISIT 7	28JAN2016	7:42	3	Double Read
					VISIT 8	28DEC2016	12:07	3	Double Read
					VISIT 11	27DEC2019	11:04	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	15DEC2014	15:38	3	Double Read
					VISIT 4	30JAN2015	7:40	3	Double Read
					VISIT 6	25JUN2015	13:35	3	Double Read
					VISIT 7	28JAN2016	7:42	3	Double Read
					VISIT 8	28DEC2016	12:07	3	Double Read
					VISIT 11	27DEC2019	11:04	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	3_4		Caudal Disc		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read
					VISIT 11	27DEC2019	11:04	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	3_4		Central Disc		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0212 Age=36 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	3_4		Central Disc		VISIT 11	27DEC2019	11:04	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read
					VISIT 11	27DEC2019	11:04	N	Double Read
Dorsal disc extrusion (Caudal Disc)	3_4		Caudal Disc		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read
					VISIT 11	27DEC2019	11:04	N	Double Read
Dorsal disc extrusion (Central Disc)	3_4		Central Disc		Baseline	15DEC2014	15:38	Y	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	Y	Double Read
					VISIT 7	28JAN2016	7:42	Y	Double Read
					VISIT 8	28DEC2016	12:07	Y	Double Read
					VISIT 11	27DEC2019	11:04	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read
					VISIT 11	27DEC2019	11:04	N	Double Read
Extradiscal fluid collection	3_4		General		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0212 Age=36 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	3_4		General		VISIT 11	27DEC2019	11:04	N	Double Read
Fracture	3_4		General		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read
					VISIT 11	27DEC2019	11:04	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	15DEC2014	15:38	14.41	Double Read
					VISIT 4	30JAN2015	7:40	15.415	Double Read
					VISIT 6	25JUN2015	13:35	16.135	Double Read
					VISIT 7	28JAN2016	7:42	16.075	Double Read
					VISIT 8	28DEC2016	12:07	16.445	Double Read
					VISIT 11	27DEC2019	11:04	17.05	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	15DEC2014	15:38	15.355	Double Read
					VISIT 4	30JAN2015	7:40	15.81	Double Read
					VISIT 6	25JUN2015	13:35	14.895	Double Read
					VISIT 7	28JAN2016	7:42	15.79	Double Read
					VISIT 8	28DEC2016	12:07	14.115	Double Read
					VISIT 11	27DEC2019	11:04	14.55	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	15DEC2014	15:38	14.405	Double Read
					VISIT 4	30JAN2015	7:40	17.535	Double Read
					VISIT 6	25JUN2015	13:35	16.11	Double Read
					VISIT 7	28JAN2016	7:42	15.6	Double Read
					VISIT 8	28DEC2016	12:07	17.775	Double Read
					VISIT 11	27DEC2019	11:04	12.055	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	15DEC2014	15:38	12.45955	Double Read
					VISIT 4	30JAN2015	7:40	12.3025	Double Read
					VISIT 6	25JUN2015	13:35	12.05365	Double Read
					VISIT 7	28JAN2016	7:42	12.8054	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0212 Age=36 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	VISIT 8	28DEC2016	12:07	13.00305	Double Read
					VISIT 11	27DEC2019	11:04	12.50685	Double Read
Height manual (mm) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	15DEC2014	15:38	11.77415	Double Read
					VISIT 4	30JAN2015	7:40	10.90515	Double Read
					VISIT 6	25JUN2015	13:35	10.90635	Double Read
					VISIT 7	28JAN2016	7:42	11.59965	Double Read
					VISIT 8	28DEC2016	12:07	12.0393	Double Read
					VISIT 11	27DEC2019	11:04	11.9324	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	15DEC2014	15:38	8.732555	Double Read
					VISIT 4	30JAN2015	7:40	8.304855	Double Read
					VISIT 6	25JUN2015	13:35	8.518375	Double Read
					VISIT 7	28JAN2016	7:42	9.19517	Double Read
					VISIT 8	28DEC2016	12:07	9.2564	Double Read
					VISIT 11	27DEC2019	11:04	8.749575	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	3_4		Caudal Disc		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read
					VISIT 11	27DEC2019	11:04	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	3_4		Central Disc		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read
					VISIT 11	27DEC2019	11:04	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0212 Age=36 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read
					VISIT 11	27DEC2019	11:04	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	3_4		Caudal Disc		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read
					VISIT 11	27DEC2019	11:04	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	3_4		Central Disc		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read
					VISIT 11	27DEC2019	11:04	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read
					VISIT 11	27DEC2019	11:04	N	Double Read
Normal lordotic LS	3_4		General		Baseline	15DEC2014	15:38	Y	Double Read
					VISIT 4	30JAN2015	7:40	Y	Double Read
					VISIT 6	25JUN2015	13:35	Y	Double Read
					VISIT 7	28JAN2016	7:42	Y	Double Read
					VISIT 8	28DEC2016	12:07	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0212 Age=36 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	3_4		General		VISIT 11	27DEC2019	11:04	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	3_4		Caudal Disc		Baseline	15DEC2014	15:38	0	Double Read
					VISIT 4	30JAN2015	7:40	0	Double Read
					VISIT 6	25JUN2015	13:35	0	Double Read
					VISIT 7	28JAN2016	7:42	0	Double Read
					VISIT 8	28DEC2016	12:07	2	Double Read
					VISIT 11	27DEC2019	11:04	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	3_4		Central Disc		Baseline	15DEC2014	15:38	0	Double Read
					VISIT 4	30JAN2015	7:40	0	Double Read
					VISIT 6	25JUN2015	13:35	0	Double Read
					VISIT 7	28JAN2016	7:42	0	Double Read
					VISIT 8	28DEC2016	12:07	0	Double Read
					VISIT 11	27DEC2019	11:04	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	15DEC2014	15:38	0	Double Read
					VISIT 4	30JAN2015	7:40	0	Double Read
					VISIT 6	25JUN2015	13:35	0	Double Read
					VISIT 7	28JAN2016	7:42	0	Double Read
					VISIT 8	28DEC2016	12:07	0	Double Read
					VISIT 11	27DEC2019	11:04	0	Double Read
Protruding osteophyte (Caudal Disc)	3_4		Caudal Disc		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read
					VISIT 11	27DEC2019	11:04	N	Double Read
Protruding osteophyte (Central Disc)	3_4		Central Disc		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0212 Age=36 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	3_4		Central Disc		VISIT 11	27DEC2019	11:04	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read
					VISIT 11	27DEC2019	11:04	N	Double Read
Relevant scoliosis	3_4		General		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read
					VISIT 11	27DEC2019	11:04	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	3_4		Caudal Disc		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read
					VISIT 11	27DEC2019	11:04	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	3_4		Central Disc		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read
					VISIT 8	28DEC2016	12:07	N	Double Read
					VISIT 11	27DEC2019	11:04	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	15DEC2014	15:38	N	Double Read
					VISIT 4	30JAN2015	7:40	N	Double Read
					VISIT 6	25JUN2015	13:35	N	Double Read
					VISIT 7	28JAN2016	7:42	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0212 Age=36 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		VISIT 8	28DEC2016	12:07	N	Double Read
					VISIT 11	27DEC2019	11:04	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	15DEC2014	15:38	66.12096	Double Read
					VISIT 4	30JAN2015	7:40	65.93632	Double Read
					VISIT 6	25JUN2015	13:35	63.65456	Double Read
					VISIT 7	28JAN2016	7:42	68.1608	Double Read
					VISIT 8	28DEC2016	12:07	102.6264	Double Read
					VISIT 11	27DEC2019	11:04	77.06272	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
T2 (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	15DEC2014	15:38	75.90496	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0212 Age=36 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	VISIT 4	30JAN2015	7:40	67.9392	Double Read
					VISIT 6	25JUN2015	13:35	57.94992	Double Read
					VISIT 7	28JAN2016	7:42	73.66432	Double Read
					VISIT 8	28DEC2016	12:07	96.8824	Double Read
					VISIT 11	27DEC2019	11:04	83.40256	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	15DEC2014	15:38	71.17504	Double Read
					VISIT 4	30JAN2015	7:40	67.5728	Double Read
					VISIT 6	25JUN2015	13:35	60.74352	Double Read
					VISIT 7	28JAN2016	7:42	73.79376	Double Read
					VISIT 8	28DEC2016	12:07	93.372	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	27DEC2019	11:04	89.3512	Double Read
					Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0212 Age=36 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	3_4		Caudal Disc		Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	3_4		Central Disc		Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	3_4		Caudal Disc		Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0212 Age=36 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	3_4		Central Disc		Baseline	15DEC2014	15:38	higher	Double Read
					VISIT 4	30JAN2015	7:40	equal	Double Read
					VISIT 6	25JUN2015	13:35	equal	Double Read
					VISIT 7	28JAN2016	7:42	equal	Double Read
					VISIT 8	28DEC2016	12:07	equal	Double Read
					VISIT 11	27DEC2019	11:04	higher	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	3_4		Caudal Disc		Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	3_4		Central Disc		Baseline	15DEC2014	15:38	higher	Double Read
					VISIT 4	30JAN2015	7:40	equal	Double Read
					VISIT 6	25JUN2015	13:35	equal	Double Read
					VISIT 7	28JAN2016	7:42	equal	Double Read
					VISIT 8	28DEC2016	12:07	equal	Double Read
					VISIT 11	27DEC2019	11:04	higher	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0212 Age=36 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	3_4		Caudal Disc		Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	3_4		Central Disc		Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0212 Age=36 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	15DEC2014	15:38	3.08419908273	Double Read
					VISIT 4	30JAN2015	7:40	10.9195379651	Double Read
					VISIT 6	25JUN2015	13:35	11.1262102939	Double Read
					VISIT 7	28JAN2016	7:42	14.787769662	Double Read
					VISIT 8	28DEC2016	12:07	23.3889587226	Double Read
					VISIT 11	27DEC2019	11:04	8.9179548157	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
T2_error (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	15DEC2014	15:38	2.65799218617	Double Read
					VISIT 4	30JAN2015	7:40	6.28341770001	Double Read
					VISIT 6	25JUN2015	13:35	11.58198743	Double Read
					VISIT 7	28JAN2016	7:42	8.6294003737	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0212 Age=36 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	VISIT 8	28DEC2016	12:07	25.3943944284	Double Read
					VISIT 11	27DEC2019	11:04	12.0751554272	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	15DEC2014	15:38	2.71393239341	Double Read
					VISIT 4	30JAN2015	7:40	3.70307457109	Double Read
					VISIT 6	25JUN2015	13:35	5.15860030575	Double Read
					VISIT 7	28JAN2016	7:42	4.49372515712	Double Read
					VISIT 8	28DEC2016	12:07	19.2904365551	Double Read
					VISIT 11	27DEC2019	11:04	13.4477119076	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0212 Age=36 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	15DEC2014	15:38	21029.5	Double Read
					VISIT 4	30JAN2015	7:40	22363.5	Double Read
					VISIT 6	25JUN2015	13:35	20527.0	Double Read
					VISIT 7	28JAN2016	7:42	22240.5	Double Read
					VISIT 8	28DEC2016	12:07	22835.0	Double Read
					VISIT 11	27DEC2019	11:04	20876.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0212 Age=36 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	15DEC2014	15:38	25117.5	Double Read
					VISIT 4	30JAN2015	7:40	23469.5	Double Read
					VISIT 6	25JUN2015	13:35	21365.0	Double Read
					VISIT 7	28JAN2016	7:42	24059.0	Double Read
					VISIT 8	28DEC2016	12:07	24288.5	Double Read
					VISIT 11	27DEC2019	11:04	21345.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read
					VISIT 11	27DEC2019	11:04		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	15DEC2014	15:38	22202.5	Double Read
					VISIT 4	30JAN2015	7:40	24640.0	Double Read
					VISIT 6	25JUN2015	13:35	20808.0	Double Read
					VISIT 7	28JAN2016	7:42	23740.5	Double Read
					VISIT 8	28DEC2016	12:07	23271.5	Double Read
					VISIT 11	27DEC2019	11:04	19658.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	15DEC2014	15:38		Double Read
					VISIT 4	30JAN2015	7:40		Double Read
					VISIT 6	25JUN2015	13:35		Double Read
					VISIT 7	28JAN2016	7:42		Double Read
					VISIT 8	28DEC2016	12:07		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0212 Age=36 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	27DEC2019	11:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0213 Age=21 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	17DEC2014	17:55		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	17DEC2014	17:55	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17DEC2014	17:55	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	17DEC2014	17:55		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	17DEC2014	17:55	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17DEC2014	17:55	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	17DEC2014	17:55		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	17DEC2014	17:55	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17DEC2014	17:55	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	17DEC2014	17:55	N	Double Read
Fracture	5_S		General		Baseline	17DEC2014	17:55	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	17DEC2014	17:55		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	17DEC2014	17:55	10.48	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	17DEC2014	17:55	13.19	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0213 Age=21 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	17DEC2014	17:55		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	17DEC2014	17:55	7.297875	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	17DEC2014	17:55	10.3772	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	17DEC2014	17:55		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	17DEC2014	17:55	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17DEC2014	17:55	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	17DEC2014	17:55		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	17DEC2014	17:55	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17DEC2014	17:55	N	Double Read
Normal lordotic LS	5_S		General		Baseline	17DEC2014	17:55	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	17DEC2014	17:55		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	17DEC2014	17:55	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0213 Age=21 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17DEC2014	17:55	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	17DEC2014	17:55		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	17DEC2014	17:55	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17DEC2014	17:55	N	Double Read
Relevant scoliosis	5_S		General		Baseline	17DEC2014	17:55	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	17DEC2014	17:55		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	17DEC2014	17:55	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	17DEC2014	17:55	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	17DEC2014	17:55		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	17DEC2014	17:55		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	17DEC2014	17:55		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	17DEC2014	17:55		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	17DEC2014	17:55	62.6872	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	17DEC2014	17:55		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0213 Age=21 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	17DEC2014	17:55		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	17DEC2014	17:55	94.74992	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	17DEC2014	17:55		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	17DEC2014	17:55		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	17DEC2014	17:55		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	17DEC2014	17:55		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	17DEC2014	17:55		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	17DEC2014	17:55		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	17DEC2014	17:55		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	17DEC2014	17:55		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0213 Age=21 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	17DEC2014	17:55	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	17DEC2014	17:55		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	17DEC2014	17:55		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	17DEC2014	17:55		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	17DEC2014	17:55		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	17DEC2014	17:55		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	17DEC2014	17:55		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	17DEC2014	17:55		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	17DEC2014	17:55		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	17DEC2014	17:55	7.37702734842	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	17DEC2014	17:55		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	17DEC2014	17:55		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0213 Age=21 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	17DEC2014	17:55	2.46871411585	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	17DEC2014	17:55		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	17DEC2014	17:55		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	17DEC2014	17:55		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	17DEC2014	17:55		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	17DEC2014	17:55		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	17DEC2014	17:55	8932.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	17DEC2014	17:55		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	17DEC2014	17:55		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	17DEC2014	17:55	13618.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	17DEC2014	17:55		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0214 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	25FEB2015	8:22	2	Double Read
					VISIT 3A	27MAY2015	16:52	2	Double Read
					VISIT 4	23JUL2015	9:51	2	Double Read
					VISIT 6	03DEC2015	14:34	2	Double Read
					VISIT 7	26MAY2016	12:13	2	Double Read
					VISIT 11	15OCT2020	11:34	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	25FEB2015	8:22	3	Double Read
					VISIT 3A	27MAY2015	16:52	2	Double Read
					VISIT 4	23JUL2015	9:51	3	Double Read
					VISIT 6	03DEC2015	14:34	4	Double Read
					VISIT 7	26MAY2016	12:13	3	Double Read
					VISIT 11	15OCT2020	11:34	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	8:22	2	Double Read
					VISIT 3A	27MAY2015	16:52	2	Double Read
					VISIT 4	23JUL2015	9:51	2	Double Read
					VISIT 6	03DEC2015	14:34	3	Double Read
					VISIT 7	26MAY2016	12:13	2	Double Read
					VISIT 11	15OCT2020	11:34	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read
					VISIT 11	15OCT2020	11:34	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0214 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 11	15OCT2020	11:34	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read
					VISIT 11	15OCT2020	11:34	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read
					VISIT 11	15OCT2020	11:34	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	25FEB2015	8:22	Y	Double Read
					VISIT 3A	27MAY2015	16:52	Y	Double Read
					VISIT 4	23JUL2015	9:51	Y	Double Read
					VISIT 6	03DEC2015	14:34	Y	Double Read
					VISIT 7	26MAY2016	12:13	Y	Double Read
					VISIT 11	15OCT2020	11:34	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read
					VISIT 11	15OCT2020	11:34	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0214 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	4_5		General		VISIT 11	15OCT2020	11:34	N	Double Read
Fracture	4_5		General		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read
					VISIT 11	15OCT2020	11:34	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	25FEB2015	8:22	12.725	Double Read
					VISIT 3A	27MAY2015	16:52	14.155	Double Read
					VISIT 4	23JUL2015	9:51	12.955	Double Read
					VISIT 6	03DEC2015	14:34	12.895	Double Read
					VISIT 7	26MAY2016	12:13	13.645	Double Read
					VISIT 11	15OCT2020	11:34	13.81	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	25FEB2015	8:22	11.61	Double Read
					VISIT 3A	27MAY2015	16:52	10.415	Double Read
					VISIT 4	23JUL2015	9:51	10.24	Double Read
					VISIT 6	03DEC2015	14:34	10.745	Double Read
					VISIT 7	26MAY2016	12:13	9.86	Double Read
					VISIT 11	15OCT2020	11:34	10.855	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	25FEB2015	8:22	13.14	Double Read
					VISIT 3A	27MAY2015	16:52	12.515	Double Read
					VISIT 4	23JUL2015	9:51	13.375	Double Read
					VISIT 6	03DEC2015	14:34	12.55	Double Read
					VISIT 7	26MAY2016	12:13	12.205	Double Read
					VISIT 11	15OCT2020	11:34	11.825	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	25FEB2015	8:22	7.56553	Double Read
					VISIT 3A	27MAY2015	16:52	7.11786	Double Read
					VISIT 4	23JUL2015	9:51	7.782585	Double Read
					VISIT 6	03DEC2015	14:34	7.89304	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0214 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	VISIT 7	26MAY2016	12:13	7.26879	Double Read
					VISIT 11	15OCT2020	11:34	7.972245	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	25FEB2015	8:22	7.06689	Double Read
					VISIT 3A	27MAY2015	16:52	6.453205	Double Read
					VISIT 4	23JUL2015	9:51	7.39871	Double Read
					VISIT 6	03DEC2015	14:34	8.507565	Double Read
					VISIT 7	26MAY2016	12:13	7.496825	Double Read
					VISIT 11	15OCT2020	11:34	7.860845	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	25FEB2015	8:22	8.51359	Double Read
					VISIT 3A	27MAY2015	16:52	10.26311	Double Read
					VISIT 4	23JUL2015	9:51	11.1768	Double Read
					VISIT 6	03DEC2015	14:34	9.905835	Double Read
					VISIT 7	26MAY2016	12:13	9.202155	Double Read
					VISIT 11	15OCT2020	11:34	10.76145	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read
					VISIT 11	15OCT2020	11:34	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read
					VISIT 11	15OCT2020	11:34	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0214 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read
					VISIT 11	15OCT2020	11:34	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read
					VISIT 11	15OCT2020	11:34	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read
					VISIT 11	15OCT2020	11:34	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read
					VISIT 11	15OCT2020	11:34	N	Double Read
Normal lordotic LS	4_5		General		Baseline	25FEB2015	8:22	Y	Double Read
					VISIT 3A	27MAY2015	16:52	Y	Double Read
					VISIT 4	23JUL2015	9:51	Y	Double Read
					VISIT 6	03DEC2015	14:34	Y	Double Read
					VISIT 7	26MAY2016	12:13	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0214 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	4_5		General		VISIT 11	15OCT2020	11:34	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	25FEB2015	8:22	0	Double Read
					VISIT 3A	27MAY2015	16:52	0	Double Read
					VISIT 4	23JUL2015	9:51	0	Double Read
					VISIT 6	03DEC2015	14:34	0	Double Read
					VISIT 7	26MAY2016	12:13	0	Double Read
					VISIT 11	15OCT2020	11:34	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	25FEB2015	8:22	0	Double Read
					VISIT 3A	27MAY2015	16:52	0	Double Read
					VISIT 4	23JUL2015	9:51	0	Double Read
					VISIT 6	03DEC2015	14:34	0	Double Read
					VISIT 7	26MAY2016	12:13	0	Double Read
					VISIT 11	15OCT2020	11:34	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	8:22	0	Double Read
					VISIT 3A	27MAY2015	16:52	0	Double Read
					VISIT 4	23JUL2015	9:51	0	Double Read
					VISIT 6	03DEC2015	14:34	0	Double Read
					VISIT 7	26MAY2016	12:13	0	Double Read
					VISIT 11	15OCT2020	11:34	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read
					VISIT 11	15OCT2020	11:34	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0214 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 11	15OCT2020	11:34	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read
					VISIT 11	15OCT2020	11:34	N	Double Read
Relevant scoliosis	4_5		General		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read
					VISIT 11	15OCT2020	11:34	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read
					VISIT 11	15OCT2020	11:34	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read
					VISIT 7	26MAY2016	12:13	N	Double Read
					VISIT 11	15OCT2020	11:34	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	8:22	N	Double Read
					VISIT 3A	27MAY2015	16:52	N	Double Read
					VISIT 4	23JUL2015	9:51	N	Double Read
					VISIT 6	03DEC2015	14:34	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0214 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	26MAY2016	12:13	N	Double Read
					VISIT 11	15OCT2020	11:34	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	25FEB2015	8:22	99.95536	Double Read
					VISIT 3A	27MAY2015	16:52	93.38912	Double Read
					VISIT 4	23JUL2015	9:51	101.22256	Double Read
					VISIT 6	03DEC2015	14:34	89.34752	Double Read
					VISIT 7	26MAY2016	12:13	95.09648	Double Read
					VISIT 11	15OCT2020	11:34	92.74688	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	25FEB2015	8:22	78.61824	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0214 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	27MAY2015	16:52	90.444	Double Read
					VISIT 4	23JUL2015	9:51	92.44752	Double Read
					VISIT 6	03DEC2015	14:34	64.66208	Double Read
					VISIT 7	26MAY2016	12:13	95.49792	Double Read
					VISIT 11	15OCT2020	11:34	80.46608	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	25FEB2015	8:22	100.6256	Double Read
					VISIT 3A	27MAY2015	16:52	100.74176	Double Read
					VISIT 4	23JUL2015	9:51	98.8344	Double Read
					VISIT 6	03DEC2015	14:34	91.6512	Double Read
					VISIT 7	26MAY2016	12:13	100.60128	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	15OCT2020	11:34	100.00304	Double Read
					Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0214 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0214 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	25FEB2015	8:22	lower	Double Read
					VISIT 3A	27MAY2015	16:52	equal	Double Read
					VISIT 4	23JUL2015	9:51	lower	Double Read
					VISIT 6	03DEC2015	14:34	lower	Double Read
					VISIT 7	26MAY2016	12:13	lower	Double Read
					VISIT 11	15OCT2020	11:34	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	25FEB2015	8:22	lower	Double Read
					VISIT 3A	27MAY2015	16:52	equal	Double Read
					VISIT 4	23JUL2015	9:51	lower	Double Read
					VISIT 6	03DEC2015	14:34	lower	Double Read
					VISIT 7	26MAY2016	12:13	lower	Double Read
					VISIT 11	15OCT2020	11:34	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0214 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0214 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	25FEB2015	8:22	2.07815865466	Double Read
					VISIT 3A	27MAY2015	16:52	10.2047766264	Double Read
					VISIT 4	23JUL2015	9:51	6.1556174622	Double Read
					VISIT 6	03DEC2015	14:34	8.14385595378	Double Read
					VISIT 7	26MAY2016	12:13	6.25106166129	Double Read
					VISIT 11	15OCT2020	11:34	11.352702565	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	25FEB2015	8:22	9.0406319008	Double Read
					VISIT 3A	27MAY2015	16:52	6.92486495669	Double Read
					VISIT 4	23JUL2015	9:51	2.63156786139	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0214 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 6	03DEC2015	14:34	7.64396127059	Double Read
					VISIT 7	26MAY2016	12:13	3.80175980975	Double Read
					VISIT 11	15OCT2020	11:34	9.4077119076	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	25FEB2015	8:22	3.24443689485	Double Read
					VISIT 3A	27MAY2015	16:52	4.36190929165	Double Read
					VISIT 4	23JUL2015	9:51	2.25544419908	Double Read
					VISIT 6	03DEC2015	14:34	1.93543740445	Double Read
					VISIT 7	26MAY2016	12:13	13.6232376423	Double Read
					VISIT 11	15OCT2020	11:34	14.598742993	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0214 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	25FEB2015	8:22	9868.5	Double Read
					VISIT 3A	27MAY2015	16:52	9994.0	Double Read
					VISIT 4	23JUL2015	9:51	9671.5	Double Read
					VISIT 6	03DEC2015	14:34	10426.5	Double Read
					VISIT 7	26MAY2016	12:13	9764.5	Double Read
					VISIT 11	15OCT2020	11:34	10108.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0214 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	25FEB2015	8:22	11844.0	Double Read
					VISIT 3A	27MAY2015	16:52	10970.5	Double Read
					VISIT 4	23JUL2015	9:51	11045.5	Double Read
					VISIT 6	03DEC2015	14:34	11213.0	Double Read
					VISIT 7	26MAY2016	12:13	12083.5	Double Read
					VISIT 11	15OCT2020	11:34	11012.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read
					VISIT 11	15OCT2020	11:34		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	25FEB2015	8:22	14646.5	Double Read
					VISIT 3A	27MAY2015	16:52	14596.0	Double Read
					VISIT 4	23JUL2015	9:51	13681.0	Double Read
					VISIT 6	03DEC2015	14:34	13208.5	Double Read
					VISIT 7	26MAY2016	12:13	13553.5	Double Read
					VISIT 11	15OCT2020	11:34	14106.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	25FEB2015	8:22		Double Read
					VISIT 3A	27MAY2015	16:52		Double Read
					VISIT 4	23JUL2015	9:51		Double Read
					VISIT 6	03DEC2015	14:34		Double Read
					VISIT 7	26MAY2016	12:13		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0214 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	15OCT2020	11:34		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0215 Age=32 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	04MAR2015	16:56	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	04MAR2015	16:56	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	04MAR2015	16:56	1	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	04MAR2015	16:56	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	04MAR2015	16:56	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	04MAR2015	16:56	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	04MAR2015	16:56	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	04MAR2015	16:56	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	04MAR2015	16:56	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	04MAR2015	16:56	N	Double Read
Fracture	4_5		General		Baseline	04MAR2015	16:56	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	04MAR2015	16:56	16.235	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	04MAR2015	16:56	14.59	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	04MAR2015	16:56	14.805	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0215 Age=32 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	04MAR2015	16:56	9.756605	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	04MAR2015	16:56	10.88645	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	04MAR2015	16:56	13.42725	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	04MAR2015	16:56	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	04MAR2015	16:56	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	04MAR2015	16:56	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	04MAR2015	16:56	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	04MAR2015	16:56	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	04MAR2015	16:56	N	Double Read
Normal lordotic LS	4_5		General		Baseline	04MAR2015	16:56	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	04MAR2015	16:56	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	04MAR2015	16:56	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0215 Age=32 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	04MAR2015	16:56	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	04MAR2015	16:56	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	04MAR2015	16:56	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	04MAR2015	16:56	N	Double Read
Relevant scoliosis	4_5		General		Baseline	04MAR2015	16:56	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	04MAR2015	16:56	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	04MAR2015	16:56	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	04MAR2015	16:56	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	04MAR2015	16:56		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	04MAR2015	16:56	58.70144	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	04MAR2015	16:56		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	04MAR2015	16:56		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	04MAR2015	16:56	65.86832	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	04MAR2015	16:56		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0215 Age=32 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	04MAR2015	16:56		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	04MAR2015	16:56	107.00576	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	04MAR2015	16:56		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	04MAR2015	16:56		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	04MAR2015	16:56		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	04MAR2015	16:56		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	04MAR2015	16:56		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	04MAR2015	16:56	higher	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	04MAR2015	16:56		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	04MAR2015	16:56		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0215 Age=32 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	04MAR2015	16:56	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	04MAR2015	16:56		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	04MAR2015	16:56		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	04MAR2015	16:56		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	04MAR2015	16:56		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	04MAR2015	16:56		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	04MAR2015	16:56	6.67811788687	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	04MAR2015	16:56		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	04MAR2015	16:56		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	04MAR2015	16:56	15.7861729234	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	04MAR2015	16:56		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	04MAR2015	16:56		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0215 Age=32 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	04MAR2015	16:56	2.46348224903	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	04MAR2015	16:56		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	04MAR2015	16:56		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	04MAR2015	16:56	16146.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	04MAR2015	16:56		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	04MAR2015	16:56		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	04MAR2015	16:56	17932.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	04MAR2015	16:56		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	04MAR2015	16:56		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	04MAR2015	16:56	20620.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	04MAR2015	16:56		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0216 Age=37 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	27APR2015	14:59	4	Double Read
					VISIT 3A	22JUL2015	13:57	4	Double Read
					VISIT 4	21AUG2015	7:43	2	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27APR2015	14:59	3	Double Read
					VISIT 3A	22JUL2015	13:57	3	Double Read
					VISIT 4	21AUG2015	7:43	4	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	27APR2015	14:59	N	Double Read
					VISIT 3A	22JUL2015	13:57	N	Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27APR2015	14:59	N	Double Read
					VISIT 3A	22JUL2015	13:57	N	Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	27APR2015	14:59	Y	Double Read
					VISIT 3A	22JUL2015	13:57	Y	Double Read
					VISIT 4	21AUG2015	7:43	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0216 Age=37 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27APR2015	14:59	N	Double Read
					VISIT 3A	22JUL2015	13:57	N	Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	27APR2015	14:59	N	Double Read
					VISIT 3A	22JUL2015	13:57	N	Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read
Fracture	5_S		General		Baseline	27APR2015	14:59	N	Double Read
					VISIT 3A	22JUL2015	13:57	N	Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	27APR2015	14:59	9.33	Double Read
					VISIT 3A	22JUL2015	13:57	10.805	Double Read
					VISIT 4	21AUG2015	7:43		Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	27APR2015	14:59	12.825	Double Read
					VISIT 3A	22JUL2015	13:57	13.31	Double Read
					VISIT 4	21AUG2015	7:43		Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	27APR2015	14:59	6.961145	Double Read
					VISIT 3A	22JUL2015	13:57	6.022465	Double Read
					VISIT 4	21AUG2015	7:43		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0216 Age=37 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	27APR2015	14:59	10.4916	Double Read
					VISIT 3A	22JUL2015	13:57	10.19035	Double Read
					VISIT 4	21AUG2015	7:43		Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57	N	Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	27APR2015	14:59	N	Double Read
					VISIT 3A	22JUL2015	13:57	N	Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27APR2015	14:59	N	Double Read
					VISIT 3A	22JUL2015	13:57	N	Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	27APR2015	14:59	N	Double Read
					VISIT 3A	22JUL2015	13:57	N	Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27APR2015	14:59	N	Double Read
					VISIT 3A	22JUL2015	13:57	N	Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0216 Age=37 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	5_S		General		Baseline	27APR2015	14:59	Y	Double Read
					VISIT 3A	22JUL2015	13:57	Y	Double Read
					VISIT 4	21AUG2015	7:43	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	27APR2015	14:59	0	Double Read
					VISIT 3A	22JUL2015	13:57	0	Double Read
					VISIT 4	21AUG2015	7:43	1	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27APR2015	14:59	0	Double Read
					VISIT 3A	22JUL2015	13:57	0	Double Read
					VISIT 4	21AUG2015	7:43	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	27APR2015	14:59	N	Double Read
					VISIT 3A	22JUL2015	13:57	N	Double Read
					VISIT 4	21AUG2015	7:43	unknown	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27APR2015	14:59	N	Double Read
					VISIT 3A	22JUL2015	13:57	N	Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read
Relevant scoliosis	5_S		General		Baseline	27APR2015	14:59	N	Double Read
					VISIT 3A	22JUL2015	13:57	N	Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	27APR2015	14:59		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0216 Age=37 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	27APR2015	14:59	N	Double Read
					VISIT 3A	22JUL2015	13:57	N	Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27APR2015	14:59	N	Double Read
					VISIT 3A	22JUL2015	13:57	N	Double Read
					VISIT 4	21AUG2015	7:43	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	27APR2015	14:59	59.43312	Double Read
					VISIT 3A	22JUL2015	13:57	75.88944	Double Read
					VISIT 4	21AUG2015	7:43		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0216 Age=37 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	27APR2015	14:59	70.79616	Double Read
					VISIT 3A	22JUL2015	13:57	72.864	Double Read
					VISIT 4	21AUG2015	7:43		Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0216 Age=37 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	27APR2015	14:59		Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43		Double Read Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	27APR2015	14:59		Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43		Double Read Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	27APR2015	14:59		Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43		Double Read Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	27APR2015	14:59		Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43		Double Read Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	27APR2015	14:59	lower	Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43	equal higher	Double Read Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	27APR2015	14:59		Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43		Double Read Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	27APR2015	14:59		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0216 Age=37 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	27APR2015	14:59		Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43		Double Read Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	27APR2015	14:59		Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43		Double Read Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	27APR2015	14:59		Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43		Double Read Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	27APR2015	14:59		Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43		Double Read Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	27APR2015	14:59		Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43		Double Read Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	27APR2015	14:59		Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43		Double Read Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	27APR2015	14:59	6.4549006285	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0216 Age=37 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	22JUL2015	13:57	3.85029386784	Double Read
					VISIT 4	21AUG2015	7:43		Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	27APR2015	14:59		Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43		Double Read Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	27APR2015	14:59		Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43		Double Read Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	27APR2015	14:59	9.56910480719	Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43		4.8658807542 Double Read Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	27APR2015	14:59		Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43		Double Read Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	27APR2015	14:59		Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43		Double Read Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	27APR2015	14:59		Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43		Double Read Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	27APR2015	14:59		Double Read
					VISIT 3A VISIT 4	22JUL2015 21AUG2015	13:57 7:43		Double Read Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0216 Age=37 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	27APR2015	14:59	7614.5	Double Read
					VISIT 3A	22JUL2015	13:57	7300.0	Double Read
					VISIT 4	21AUG2015	7:43		Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	27APR2015	14:59	12119.5	Double Read
					VISIT 3A	22JUL2015	13:57	13059.5	Double Read
					VISIT 4	21AUG2015	7:43		Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	27APR2015	14:59		Double Read
					VISIT 3A	22JUL2015	13:57		Double Read
					VISIT 4	21AUG2015	7:43		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0217 Age=29 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	27MAY2015	16:07	2	Double Read
					VISIT 4	14JUL2015	14:10	3	Double Read
					VISIT 6	08DEC2015	13:13	3	Double Read
					VISIT 7	11MAY2016	13:20	2	Double Read
					VISIT 8	27APR2017	13:28	2	Double Read
					VISIT 11	01JUL2020	13:17	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	27MAY2015	16:07	3	Double Read
					VISIT 4	14JUL2015	14:10	4	Double Read
					VISIT 6	08DEC2015	13:13	4	Double Read
					VISIT 7	11MAY2016	13:20	3	Double Read
					VISIT 8	27APR2017	13:28	3	Double Read
					VISIT 11	01JUL2020	13:17	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	27MAY2015	16:07	2	Double Read
					VISIT 4	14JUL2015	14:10	3	Double Read
					VISIT 6	08DEC2015	13:13	3	Double Read
					VISIT 7	11MAY2016	13:20	2	Double Read
					VISIT 8	27APR2017	13:28	2	Double Read
					VISIT 11	01JUL2020	13:17	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	N	Double Read
					VISIT 11	01JUL2020	13:17	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0217 Age=29 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 11	01JUL2020	13:17	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	N	Double Read
					VISIT 11	01JUL2020	13:17	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	Y	Double Read
					VISIT 11	01JUL2020	13:17	Y	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	27MAY2015	16:07	Y	Double Read
					VISIT 4	14JUL2015	14:10	Y	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	Y	Double Read
					VISIT 11	01JUL2020	13:17	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	N	Double Read
					VISIT 11	01JUL2020	13:17	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0217 Age=29 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	4_5		General		VISIT 11	01JUL2020	13:17	N	Double Read
Fracture	4_5		General		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	N	Double Read
					VISIT 11	01JUL2020	13:17	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	27MAY2015	16:07	10.235	Double Read
					VISIT 4	14JUL2015	14:10	10.14	Double Read
					VISIT 6	08DEC2015	13:13	9.86	Double Read
					VISIT 7	11MAY2016	13:20	9.395	Double Read
					VISIT 8	27APR2017	13:28	10.06	Double Read
					VISIT 11	01JUL2020	13:17	9.49	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	27MAY2015	16:07	10.0	Double Read
					VISIT 4	14JUL2015	14:10	9.655	Double Read
					VISIT 6	08DEC2015	13:13	9.34	Double Read
					VISIT 7	11MAY2016	13:20	9.76	Double Read
					VISIT 8	27APR2017	13:28	9.09	Double Read
					VISIT 11	01JUL2020	13:17	8.48	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	27MAY2015	16:07	11.495	Double Read
					VISIT 4	14JUL2015	14:10	10.145	Double Read
					VISIT 6	08DEC2015	13:13	11.885	Double Read
					VISIT 7	11MAY2016	13:20	11.47	Double Read
					VISIT 8	27APR2017	13:28	10.42	Double Read
					VISIT 11	01JUL2020	13:17	11.09	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	27MAY2015	16:07	8.446255	Double Read
					VISIT 4	14JUL2015	14:10	7.88849	Double Read
					VISIT 6	08DEC2015	13:13	7.913975	Double Read
					VISIT 7	11MAY2016	13:20	7.945185	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0217 Age=29 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	VISIT 8	27APR2017	13:28	7.78524	Double Read
					VISIT 11	01JUL2020	13:17	8.31893	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	27MAY2015	16:07	8.75435	Double Read
					VISIT 4	14JUL2015	14:10	7.325155	Double Read
					VISIT 6	08DEC2015	13:13	8.063865	Double Read
					VISIT 7	11MAY2016	13:20	7.21293	Double Read
					VISIT 8	27APR2017	13:28	7.39215	Double Read
					VISIT 11	01JUL2020	13:17	7.203335	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	27MAY2015	16:07	10.44905	Double Read
					VISIT 4	14JUL2015	14:10	8.909295	Double Read
					VISIT 6	08DEC2015	13:13	9.3135	Double Read
					VISIT 7	11MAY2016	13:20	9.22871	Double Read
					VISIT 8	27APR2017	13:28	8.400615	Double Read
					VISIT 11	01JUL2020	13:17	8.552615	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	N	Double Read
					VISIT 11	01JUL2020	13:17	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	N	Double Read
					VISIT 11	01JUL2020	13:17	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0217 Age=29 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	N	Double Read
					VISIT 11	01JUL2020	13:17	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	N	Double Read
					VISIT 11	01JUL2020	13:17	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	N	Double Read
					VISIT 11	01JUL2020	13:17	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	N	Double Read
					VISIT 11	01JUL2020	13:17	N	Double Read
Normal lordotic LS	4_5		General		Baseline	27MAY2015	16:07	Y	Double Read
					VISIT 4	14JUL2015	14:10	Y	Double Read
					VISIT 6	08DEC2015	13:13	Y	Double Read
					VISIT 7	11MAY2016	13:20	Y	Double Read
					VISIT 8	27APR2017	13:28	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0217 Age=29 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	4_5		General		VISIT 11	01JUL2020	13:17	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	27MAY2015	16:07	0	Double Read
					VISIT 4	14JUL2015	14:10	0	Double Read
					VISIT 6	08DEC2015	13:13	0	Double Read
					VISIT 7	11MAY2016	13:20	0	Double Read
					VISIT 8	27APR2017	13:28	0	Double Read
					VISIT 11	01JUL2020	13:17	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	27MAY2015	16:07	0	Double Read
					VISIT 4	14JUL2015	14:10	0	Double Read
					VISIT 6	08DEC2015	13:13	0	Double Read
					VISIT 7	11MAY2016	13:20	0	Double Read
					VISIT 8	27APR2017	13:28	0	Double Read
					VISIT 11	01JUL2020	13:17	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	27MAY2015	16:07	0	Double Read
					VISIT 4	14JUL2015	14:10	0	Double Read
					VISIT 6	08DEC2015	13:13	0	Double Read
					VISIT 7	11MAY2016	13:20	0	Double Read
					VISIT 8	27APR2017	13:28	0	Double Read
					VISIT 11	01JUL2020	13:17	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	N	Double Read
					VISIT 11	01JUL2020	13:17	Y	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0217 Age=29 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 11	01JUL2020	13:17	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	N	Double Read
					VISIT 11	01JUL2020	13:17	N	Double Read
Relevant scoliosis	4_5		General		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	N	Double Read
					VISIT 11	01JUL2020	13:17	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	N	Double Read
					VISIT 11	01JUL2020	13:17	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read
					VISIT 8	27APR2017	13:28	N	Double Read
					VISIT 11	01JUL2020	13:17	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	27MAY2015	16:07	N	Double Read
					VISIT 4	14JUL2015	14:10	N	Double Read
					VISIT 6	08DEC2015	13:13	N	Double Read
					VISIT 7	11MAY2016	13:20	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0217 Age=29 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	27APR2017	13:28	N	Double Read
					VISIT 11	01JUL2020	13:17	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	27MAY2015	16:07	84.04368	Double Read
					VISIT 4	14JUL2015	14:10	77.05632	Double Read
					VISIT 6	08DEC2015	13:13	89.20992	Double Read
					VISIT 7	11MAY2016	13:20	74.08048	Double Read
					VISIT 8	27APR2017	13:28	82.54592	Double Read
					VISIT 11	01JUL2020	13:17	84.08896	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	27MAY2015	16:07	79.18224	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0217 Age=29 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 4	14JUL2015	14:10	70.22592	Double Read
					VISIT 6	08DEC2015	13:13	75.2368	Double Read
					VISIT 7	11MAY2016	13:20	76.41168	Double Read
					VISIT 8	27APR2017	13:28	76.2176	Double Read
					VISIT 11	01JUL2020	13:17	74.63792	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	27MAY2015	16:07	95.02464	Double Read
					VISIT 4	14JUL2015	14:10	80.03168	Double Read
					VISIT 6	08DEC2015	13:13	84.97872	Double Read
					VISIT 7	11MAY2016	13:20	83.63936	Double Read
					VISIT 8	27APR2017	13:28	82.1376	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	01JUL2020	13:17	72.0064	Double Read
					Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0217 Age=29 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0217 Age=29 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	27MAY2015	16:07	lower	Double Read
					VISIT 4	14JUL2015	14:10	lower	Double Read
					VISIT 6	08DEC2015	13:13	lower	Double Read
					VISIT 7	11MAY2016	13:20	lower	Double Read
					VISIT 8	27APR2017	13:28	lower	Double Read
					VISIT 11	01JUL2020	13:17	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	27MAY2015	16:07	lower	Double Read
					VISIT 4	14JUL2015	14:10	lower	Double Read
					VISIT 6	08DEC2015	13:13	lower	Double Read
					VISIT 7	11MAY2016	13:20	lower	Double Read
					VISIT 8	27APR2017	13:28	lower	Double Read
					VISIT 11	01JUL2020	13:17	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0217 Age=29 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0217 Age=29 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	27MAY2015	16:07	2.9289689145	Double Read
					VISIT 4	14JUL2015	14:10	4.7902157295	Double Read
					VISIT 6	08DEC2015	13:13	8.9624596568	Double Read
					VISIT 7	11MAY2016	13:20	2.8820587735	Double Read
					VISIT 8	27APR2017	13:28	5.4357057924	Double Read
					VISIT 11	01JUL2020	13:17	8.3611686767	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	27MAY2015	16:07	1.9628945133	Double Read
					VISIT 4	14JUL2015	14:10	6.1717886869	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0217 Age=29 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 6	08DEC2015	13:13	8.05446577204	Double Read
					VISIT 7	11MAY2016	13:20	9.76728384574	Double Read
					VISIT 8	27APR2017	13:28	4.11118736198	Double Read
					VISIT 11	01JUL2020	13:17	9.39923900119	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	27MAY2015	16:07	5.44985901138	Double Read
					VISIT 4	14JUL2015	14:10	3.47281127909	Double Read
					VISIT 6	08DEC2015	13:13	3.68042806183	Double Read
					VISIT 7	11MAY2016	13:20	5.26826567012	Double Read
					VISIT 8	27APR2017	13:28	4.43538644471	Double Read
					VISIT 11	01JUL2020	13:17	5.19034482758	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0217 Age=29 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	27MAY2015	16:07	10827.5	Double Read
					VISIT 4	14JUL2015	14:10	9343.5	Double Read
					VISIT 6	08DEC2015	13:13	10191.5	Double Read
					VISIT 7	11MAY2016	13:20	10240.5	Double Read
					VISIT 8	27APR2017	13:28	9725.0	Double Read
					VISIT 11	01JUL2020	13:17	9505.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0217 Age=29 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	VISIT 11	01JUL2020	13:17		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	27MAY2015	16:07	12957.5	Double Read
					VISIT 4	14JUL2015	14:10	11104.0	Double Read
					VISIT 6	08DEC2015	13:13	11250.5	Double Read
					VISIT 7	11MAY2016	13:20	11761.0	Double Read
					VISIT 8	27APR2017	13:28	10448.5	Double Read
					VISIT 11	01JUL2020	13:17	10727.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read
					VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	27MAY2015	16:07	16153.0	Double Read
					VISIT 4	14JUL2015	14:10	14046.0	Double Read
					VISIT 6	08DEC2015	13:13	14328.5	Double Read
					VISIT 7	11MAY2016	13:20	14923.0	Double Read
					VISIT 8	27APR2017	13:28	14963.0	Double Read
					VISIT 11	01JUL2020	13:17	14257.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	27MAY2015	16:07		Double Read
					VISIT 4	14JUL2015	14:10		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0217 Age=29 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 6	08DEC2015	13:13		Double Read
					VISIT 7	11MAY2016	13:20		Double Read
					VISIT 8	27APR2017	13:28		Double Read
					VISIT 11	01JUL2020	13:17		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0218 Age=55 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	16JUN2015	13:54		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	16JUN2015	13:54	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16JUN2015	13:54	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	16JUN2015	13:54		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	16JUN2015	13:54	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16JUN2015	13:54	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	16JUN2015	13:54		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	16JUN2015	13:54	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16JUN2015	13:54	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	16JUN2015	13:54	N	Double Read
Fracture	5_S		General		Baseline	16JUN2015	13:54	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	16JUN2015	13:54		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16JUN2015	13:54	15.11	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16JUN2015	13:54	12.49	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0218 Age=55 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	16JUN2015	13:54		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16JUN2015	13:54	9.152915	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16JUN2015	13:54	11.03415	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	16JUN2015	13:54		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	16JUN2015	13:54	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16JUN2015	13:54	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	16JUN2015	13:54		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	16JUN2015	13:54	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16JUN2015	13:54	N	Double Read
Normal lordotic LS	5_S		General		Baseline	16JUN2015	13:54	N	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	16JUN2015	13:54		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	16JUN2015	13:54	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0218 Age=55 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16JUN2015	13:54	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	16JUN2015	13:54		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	16JUN2015	13:54	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16JUN2015	13:54	N	Double Read
Relevant scoliosis	5_S		General		Baseline	16JUN2015	13:54	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	16JUN2015	13:54		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	16JUN2015	13:54	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16JUN2015	13:54	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	16JUN2015	13:54		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	16JUN2015	13:54		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	16JUN2015	13:54		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	16JUN2015	13:54		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16JUN2015	13:54	54.79376	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	16JUN2015	13:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0218 Age=55 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	16JUN2015	13:54		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16JUN2015	13:54	61.87904	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	16JUN2015	13:54		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	16JUN2015	13:54		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	16JUN2015	13:54		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	16JUN2015	13:54		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	16JUN2015	13:54		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	16JUN2015	13:54		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	16JUN2015	13:54		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	16JUN2015	13:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0218 Age=55 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	16JUN2015	13:54	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	16JUN2015	13:54		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	16JUN2015	13:54		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	16JUN2015	13:54		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	16JUN2015	13:54		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	16JUN2015	13:54		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	16JUN2015	13:54		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	16JUN2015	13:54		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	16JUN2015	13:54		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16JUN2015	13:54	6.79463224053	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	16JUN2015	13:54		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	16JUN2015	13:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0218 Age=55 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16JUN2015	13:54	10.3634312893	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	16JUN2015	13:54		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	16JUN2015	13:54		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	16JUN2015	13:54		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	16JUN2015	13:54		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	16JUN2015	13:54		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16JUN2015	13:54	13036.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	16JUN2015	13:54		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	16JUN2015	13:54		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16JUN2015	13:54	14268.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	16JUN2015	13:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05	2	Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	10JUN2015	17:37	3	Double Read
					VISIT 3A	24SEP2015	15:15	4	Double Read
					VISIT 4	04NOV2015	8:13	3	Double Read
					VISIT 6	04APR2016	10:54	3	Double Read
					VISIT 7	22AUG2016	14:05	3	Double Read
					VISIT 8	20SEP2017	11:26	4	Double Read
					VISIT 11	26AUG2020	13:13	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	10JUN2015	17:37	2	Double Read
					VISIT 3A	24SEP2015	15:15	2	Double Read
					VISIT 4	04NOV2015	8:13	2	Double Read
					VISIT 6	04APR2016	10:54	2	Double Read
					VISIT 7	22AUG2016	14:05	2	Double Read
					VISIT 8	20SEP2017	11:26	2	Double Read
					VISIT 11	26AUG2020	13:13	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
					VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	10JUN2015	17:37	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	24SEP2015	15:15	N	Double Read
					VISIT 4	04NOV2015	8:13	N	Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
					VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26	N	Double Read
					VISIT 11	26AUG2020	13:13	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	10JUN2015	17:37	N	Double Read
					VISIT 3A	24SEP2015	15:15	N	Double Read
					VISIT 4	04NOV2015	8:13	N	Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
					VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	26AUG2020	13:13	N	Double Read
					Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
					VISIT 7	22AUG2016	14:05	N	Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
					Baseline	10JUN2015	17:37	Y	Double Read
					VISIT 3A	24SEP2015	15:15	Y	Double Read
					VISIT 4	04NOV2015	8:13	Y	Double Read
					VISIT 6	04APR2016	10:54	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26	N	Double Read
					VISIT 11	26AUG2020	13:13	N	Double Read
					Baseline	10JUN2015	17:37	N	Double Read
					VISIT 3A	24SEP2015	15:15	N	Double Read
					VISIT 4	04NOV2015	8:13	N	Double Read
					VISIT 6	04APR2016	10:54	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26	N	Double Read
					VISIT 11	26AUG2020	13:13	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	10JUN2015	17:37	N	Double Read
					VISIT 3A	24SEP2015	15:15	N	Double Read
					VISIT 4	04NOV2015	8:13	N	Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
					VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26	N	Double Read
					VISIT 11	26AUG2020	13:13	N	Double Read
Fracture	5_S		General		Baseline	10JUN2015	17:37	N	Double Read
					VISIT 3A	24SEP2015	15:15	N	Double Read
					VISIT 4	04NOV2015	8:13	N	Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
					VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26	N	Double Read
					VISIT 11	26AUG2020	13:13	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	10JUN2015	17:37	11.53	Double Read
					VISIT 3A	24SEP2015	15:15	11.405	Double Read
					VISIT 4	04NOV2015	8:13	12.225	Double Read
					VISIT 6	04APR2016	10:54	12.825	Double Read
					VISIT 7	22AUG2016	14:05	13.605	Double Read
					VISIT 8	20SEP2017	11:26	12.875	Double Read
					VISIT 11	26AUG2020	13:13	12.71	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	10JUN2015	17:37	13.655	Double Read
					VISIT 3A	24SEP2015	15:15	14.225	Double Read
					VISIT 4	04NOV2015	8:13	14.015	Double Read
					VISIT 6	04APR2016	10:54	13.185	Double Read
					VISIT 7	22AUG2016	14:05	13.4	Double Read
					VISIT 8	20SEP2017	11:26	13.45	Double Read
					VISIT 11	26AUG2020	13:13	12.93	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	10JUN2015	17:37	9.51788	Double Read
					VISIT 3A	24SEP2015	15:15	9.66778	Double Read
					VISIT 4	04NOV2015	8:13	9.727705	Double Read
					VISIT 6	04APR2016	10:54	10.6794	Double Read
					VISIT 7	22AUG2016	14:05	9.68129	Double Read
					VISIT 8	20SEP2017	11:26	10.24715	Double Read
					VISIT 11	26AUG2020	13:13	9.78952	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	10JUN2015	17:37	10.41345	Double Read
					VISIT 3A	24SEP2015	15:15	11.03835	Double Read
					VISIT 4	04NOV2015	8:13	10.622675	Double Read
					VISIT 6	04APR2016	10:54	10.7978	Double Read
					VISIT 7	22AUG2016	14:05	10.93165	Double Read
					VISIT 8	20SEP2017	11:26	10.59945	Double Read
					VISIT 11	26AUG2020	13:13	11.51065	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
					VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	10JUN2015	17:37	N	Double Read
					VISIT 3A	24SEP2015	15:15	N	Double Read
					VISIT 4	04NOV2015	8:13	N	Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
					VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26	N	Double Read
					VISIT 11	26AUG2020	13:13	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	10JUN2015	17:37	N	Double Read
					VISIT 3A	24SEP2015	15:15	N	Double Read
					VISIT 4	04NOV2015	8:13	N	Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
					VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26	N	Double Read
					VISIT 11	26AUG2020	13:13	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
					VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	10JUN2015	17:37	N	Double Read
					VISIT 3A	24SEP2015	15:15	N	Double Read
					VISIT 4	04NOV2015	8:13	N	Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
					VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26	N	Double Read
					VISIT 11	26AUG2020	13:13	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	10JUN2015	17:37	N	Double Read
					VISIT 3A	24SEP2015	15:15	N	Double Read
					VISIT 4	04NOV2015	8:13	N	Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
					VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26	N	Double Read
					VISIT 11	26AUG2020	13:13	N	Double Read
Normal lordotic LS	5_S		General		Baseline	10JUN2015	17:37	Y	Double Read
					VISIT 3A	24SEP2015	15:15	Y	Double Read
					VISIT 4	04NOV2015	8:13	Y	Double Read
					VISIT 6	04APR2016	10:54	Y	Double Read
					VISIT 7	22AUG2016	14:05	Y	Double Read
					VISIT 8	20SEP2017	11:26	Y	Double Read
					VISIT 11	26AUG2020	13:13	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54	0	Double Read
					VISIT 7	22AUG2016	14:05	0	Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	10JUN2015	17:37	0	Double Read
					VISIT 3A	24SEP2015	15:15	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	04NOV2015	8:13	0	Double Read
					VISIT 6	04APR2016	10:54	2	Double Read
					VISIT 7	22AUG2016	14:05	0	Double Read
					VISIT 8	20SEP2017	11:26	0	Double Read
					VISIT 11	26AUG2020	13:13	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	10JUN2015	17:37	0	Double Read
					VISIT 3A	24SEP2015	15:15	0	Double Read
					VISIT 4	04NOV2015	8:13	0	Double Read
					VISIT 6	04APR2016	10:54	0	Double Read
					VISIT 7	22AUG2016	14:05	0	Double Read
					VISIT 8	20SEP2017	11:26	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 11	26AUG2020	13:13	0	Double Read
					Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
					VISIT 7	22AUG2016	14:05	N	Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
					Baseline	10JUN2015	17:37	N	Double Read
					VISIT 3A	24SEP2015	15:15	N	Double Read
					VISIT 4	04NOV2015	8:13	N	Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26	N	Double Read
					VISIT 11	26AUG2020	13:13	N	Double Read
					VISIT 3A	24SEP2015	15:15	N	Double Read
					VISIT 4	04NOV2015	8:13	N	Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
					VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	20SEP2017	11:26	N	Double Read
					VISIT 11	26AUG2020	13:13	N	Double Read
Relevant scoliosis	5_S		General		Baseline	10JUN2015	17:37	N	Double Read
					VISIT 3A	24SEP2015	15:15	N	Double Read
					VISIT 4	04NOV2015	8:13	N	Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
					VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26	N	Double Read
					VISIT 11	26AUG2020	13:13	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
					VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	10JUN2015	17:37	N	Double Read
					VISIT 3A	24SEP2015	15:15	N	Double Read
					VISIT 4	04NOV2015	8:13	N	Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
					VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26	N	Double Read
					VISIT 11	26AUG2020	13:13	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	10JUN2015	17:37	N	Double Read
					VISIT 3A	24SEP2015	15:15	N	Double Read
					VISIT 4	04NOV2015	8:13	N	Double Read
					VISIT 6	04APR2016	10:54	N	Double Read
					VISIT 7	22AUG2016	14:05	N	Double Read
					VISIT 8	20SEP2017	11:26	N	Double Read
					VISIT 11	26AUG2020	13:13	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	10JUN2015	17:37	65.03872	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	24SEP2015	15:15	92.71632	Double Read
					VISIT 4	04NOV2015	8:13	63.56976	Double Read
					VISIT 6	04APR2016	10:54	60.31776	Double Read
					VISIT 7	22AUG2016	14:05	67.05088	Double Read
					VISIT 8	20SEP2017	11:26	66.9568	Double Read
					VISIT 11	26AUG2020	13:13	75.26256	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 11	26AUG2020	13:13		Double Read
					Baseline	10JUN2015	17:37	91.82512	Double Read
					VISIT 3A	24SEP2015	15:15	88.07792	Double Read
					VISIT 4	04NOV2015	8:13	97.98352	Double Read
					VISIT 6	04APR2016	10:54	90.94336	Double Read
					VISIT 7	22AUG2016	14:05	93.57216	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	20SEP2017	11:26	100.64608	Double Read
					VISIT 11	26AUG2020	13:13	102.20144	Double Read
					VISIT 3A	24SEP2015	15:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	26AUG2020	13:13		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	10JUN2015	17:37	lower	Double Read
					VISIT 3A	24SEP2015	15:15	lower	Double Read
					VISIT 4	04NOV2015	8:13	lower	Double Read
					VISIT 6	04APR2016	10:54	lower	Double Read
					VISIT 7	22AUG2016	14:05	lower	Double Read
					VISIT 8	20SEP2017	11:26	lower	Double Read
					VISIT 11	26AUG2020	13:13	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	10JUN2015	17:37	7.6231968744	Double Read
					VISIT 3A	24SEP2015	15:15	8.9236147443	Double Read
					VISIT 4	04NOV2015	8:13	3.8729403771	Double Read
					VISIT 6	04APR2016	10:54	3.4419228809	Double Read
					VISIT 7	22AUG2016	14:05	5.2752777305	Double Read
					VISIT 8	20SEP2017	11:26	10.910174961	Double Read
					VISIT 11	26AUG2020	13:13	9.318355699	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	10JUN2015	17:37	7.19098352302	Double Read
					VISIT 3A	24SEP2015	15:15	2.79559707831	Double Read
					VISIT 4	04NOV2015	8:13	2.26488194326	Double Read
					VISIT 6	04APR2016	10:54	3.79528452523	Double Read
					VISIT 7	22AUG2016	14:05	3.6485136742	Double Read
					VISIT 8	20SEP2017	11:26	7.85629352813	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 11	26AUG2020	13:13		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	10JUN2015	17:37	10721.0	Double Read
					VISIT 3A	24SEP2015	15:15	10669.0	Double Read
					VISIT 4	04NOV2015	8:13	11077.5	Double Read
					VISIT 6	04APR2016	10:54	11555.5	Double Read
					VISIT 7	22AUG2016	14:05	11893.5	Double Read
					VISIT 8	20SEP2017	11:26	10931.0	Double Read
					VISIT 11	26AUG2020	13:13	10554.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0219 Age=24 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
Volume (mm ³) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read
Volume (mm ³) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	10JUN2015	17:37	10543.5	Double Read
					VISIT 3A	24SEP2015	15:15	12146.5	Double Read
					VISIT 4	04NOV2015	8:13	12408.5	Double Read
					VISIT 6	04APR2016	10:54	12315.0	Double Read
					VISIT 7	22AUG2016	14:05	11975.5	Double Read
					VISIT 8	20SEP2017	11:26	12035.5	Double Read
					VISIT 11	26AUG2020	13:13	12309.0	Double Read
Volume (mm ³) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	10JUN2015	17:37		Double Read
					VISIT 3A	24SEP2015	15:15		Double Read
					VISIT 4	04NOV2015	8:13		Double Read
					VISIT 6	04APR2016	10:54		Double Read
					VISIT 7	22AUG2016	14:05		Double Read
					VISIT 8	20SEP2017	11:26		Double Read
					VISIT 11	26AUG2020	13:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0220 Age=44 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirschmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	12AUG2015	10:50	3	Double Read
					VISIT 4	29SEP2015	11:35	2	Double Read
					VISIT 6	26JAN2016	12:53	2	Double Read
					VISIT 7	04AUG2016	13:49	2	Double Read
					VISIT 8	19JUL2017	13:03	2	Double Read
					VISIT 11	02SEP2020	11:47	2	Double Read
Disc degeneration grading (Pfirschmann) (Central Disc)	4_5		Central Disc		Baseline	12AUG2015	10:50	4	Double Read
					VISIT 4	29SEP2015	11:35	4	Double Read
					VISIT 6	26JAN2016	12:53	3	Double Read
					VISIT 7	04AUG2016	13:49	3	Double Read
					VISIT 8	19JUL2017	13:03	3	Double Read
					VISIT 11	02SEP2020	11:47	3	Double Read
Disc degeneration grading (Pfirschmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	12AUG2015	10:50	2	Double Read
					VISIT 4	29SEP2015	11:35	2	Double Read
					VISIT 6	26JAN2016	12:53	2	Double Read
					VISIT 7	04AUG2016	13:49	2	Double Read
					VISIT 8	19JUL2017	13:03	2	Double Read
					VISIT 11	02SEP2020	11:47	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read
					VISIT 11	02SEP2020	11:47	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	Y	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0220 Age=44 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 11	02SEP2020	11:47	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read
					VISIT 11	02SEP2020	11:47	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read
					VISIT 11	02SEP2020	11:47	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	12AUG2015	10:50	Y	Double Read
					VISIT 4	29SEP2015	11:35	Y	Double Read
					VISIT 6	26JAN2016	12:53	Y	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	Y	Double Read
					VISIT 11	02SEP2020	11:47	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read
					VISIT 11	02SEP2020	11:47	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0220 Age=44 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	4_5		General		VISIT 11	02SEP2020	11:47	N	Double Read
Fracture	4_5		General		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read
					VISIT 11	02SEP2020	11:47	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35	15.845	Double Read
					VISIT 6	26JAN2016	12:53	15.53	Double Read
					VISIT 7	04AUG2016	13:49	15.28	Double Read
					VISIT 8	19JUL2017	13:03	16.225	Double Read
					VISIT 11	02SEP2020	11:47	17.87	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35	14.57	Double Read
					VISIT 6	26JAN2016	12:53	14.4	Double Read
					VISIT 7	04AUG2016	13:49	14.295	Double Read
					VISIT 8	19JUL2017	13:03	14.22	Double Read
					VISIT 11	02SEP2020	11:47	12.575	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35	13.67	Double Read
					VISIT 6	26JAN2016	12:53	14.12	Double Read
					VISIT 7	04AUG2016	13:49	14.54	Double Read
					VISIT 8	19JUL2017	13:03	15.405	Double Read
					VISIT 11	02SEP2020	11:47	14.425	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35	10.6854	Double Read
					VISIT 6	26JAN2016	12:53	10.8266	Double Read
					VISIT 7	04AUG2016	13:49	11.6134	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0220 Age=44 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	VISIT 8	19JUL2017	13:03	11.2771	Double Read
					VISIT 11	02SEP2020	11:47	11.69075	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35	9.185825	Double Read
					VISIT 6	26JAN2016	12:53	9.244	Double Read
					VISIT 7	04AUG2016	13:49	9.19014	Double Read
					VISIT 8	19JUL2017	13:03	9.008695	Double Read
					VISIT 11	02SEP2020	11:47	8.169285	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35	11.031755	Double Read
					VISIT 6	26JAN2016	12:53	12.6024	Double Read
					VISIT 7	04AUG2016	13:49	12.4784	Double Read
					VISIT 8	19JUL2017	13:03	12.1898	Double Read
					VISIT 11	02SEP2020	11:47	12.56275	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read
					VISIT 11	02SEP2020	11:47	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read
					VISIT 11	02SEP2020	11:47	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0220 Age=44 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read
					VISIT 11	02SEP2020	11:47	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read
					VISIT 11	02SEP2020	11:47	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read
					VISIT 11	02SEP2020	11:47	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read
					VISIT 11	02SEP2020	11:47	N	Double Read
Normal lordotic LS	4_5		General		Baseline	12AUG2015	10:50	Y	Double Read
					VISIT 4	29SEP2015	11:35	Y	Double Read
					VISIT 6	26JAN2016	12:53	Y	Double Read
					VISIT 7	04AUG2016	13:49	Y	Double Read
					VISIT 8	19JUL2017	13:03	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0220 Age=44 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	4_5		General		VISIT 11	02SEP2020	11:47	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	12AUG2015	10:50	0	Double Read
					VISIT 4	29SEP2015	11:35	2	Double Read
					VISIT 6	26JAN2016	12:53	0	Double Read
					VISIT 7	04AUG2016	13:49	0	Double Read
					VISIT 8	19JUL2017	13:03	0	Double Read
					VISIT 11	02SEP2020	11:47	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	12AUG2015	10:50	0	Double Read
					VISIT 4	29SEP2015	11:35	2	Double Read
					VISIT 6	26JAN2016	12:53	0	Double Read
					VISIT 7	04AUG2016	13:49	0	Double Read
					VISIT 8	19JUL2017	13:03	1	Double Read
					VISIT 11	02SEP2020	11:47	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	12AUG2015	10:50	0	Double Read
					VISIT 4	29SEP2015	11:35	0	Double Read
					VISIT 6	26JAN2016	12:53	0	Double Read
					VISIT 7	04AUG2016	13:49	0	Double Read
					VISIT 8	19JUL2017	13:03	0	Double Read
					VISIT 11	02SEP2020	11:47	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read
					VISIT 11	02SEP2020	11:47	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0220 Age=44 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 11	02SEP2020	11:47	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read
					VISIT 11	02SEP2020	11:47	N	Double Read
Relevant scoliosis	4_5		General		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read
					VISIT 11	02SEP2020	11:47	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read
					VISIT 11	02SEP2020	11:47	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read
					VISIT 8	19JUL2017	13:03	N	Double Read
					VISIT 11	02SEP2020	11:47	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	12AUG2015	10:50	N	Double Read
					VISIT 4	29SEP2015	11:35	N	Double Read
					VISIT 6	26JAN2016	12:53	N	Double Read
					VISIT 7	04AUG2016	13:49	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0220 Age=44 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	19JUL2017	13:03	N	Double Read
					VISIT 11	02SEP2020	11:47	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35	75.07008	Double Read
					VISIT 6	26JAN2016	12:53	80.7824	Double Read
					VISIT 7	04AUG2016	13:49	71.608	Double Read
					VISIT 8	19JUL2017	13:03	71.73344	Double Read
					VISIT 11	02SEP2020	11:47	73.38032	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	12AUG2015	10:50		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0220 Age=44 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 4	29SEP2015	11:35	68.81536	Double Read
					VISIT 6	26JAN2016	12:53	67.18928	Double Read
					VISIT 7	04AUG2016	13:49	64.4992	Double Read
					VISIT 8	19JUL2017	13:03	67.29648	Double Read
					VISIT 11	02SEP2020	11:47	72.72976	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35	83.85168	Double Read
					VISIT 6	26JAN2016	12:53	81.39808	Double Read
					VISIT 7	04AUG2016	13:49	78.32304	Double Read
					VISIT 8	19JUL2017	13:03	78.21024	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	02SEP2020	11:47	77.51248	Double Read
					Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0220 Age=44 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0220 Age=44 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	12AUG2015	10:50	lower	Double Read
					VISIT 4	29SEP2015	11:35	lower	Double Read
					VISIT 6	26JAN2016	12:53	lower	Double Read
					VISIT 7	04AUG2016	13:49	lower	Double Read
					VISIT 8	19JUL2017	13:03	lower	Double Read
					VISIT 11	02SEP2020	11:47	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	12AUG2015	10:50	lower	Double Read
					VISIT 4	29SEP2015	11:35	lower	Double Read
					VISIT 6	26JAN2016	12:53	lower	Double Read
					VISIT 7	04AUG2016	13:49	lower	Double Read
					VISIT 8	19JUL2017	13:03	lower	Double Read
					VISIT 11	02SEP2020	11:47	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0220 Age=44 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0220 Age=44 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35	4.6970069645	Double Read
					VISIT 6	26JAN2016	12:53	7.6385663326	Double Read
					VISIT 7	04AUG2016	13:49	10.4467470698	Double Read
					VISIT 8	19JUL2017	13:03	7.1139731612	Double Read
					VISIT 11	02SEP2020	11:47	14.829284865	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35	4.45695940208	Double Read
					VISIT 6	26JAN2016	12:53	7.69680992017	Double Read
					VISIT 7	04AUG2016	13:49	15.4706981484	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0220 Age=44 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 8	19JUL2017	13:03	10.3779921862	Double Read
					VISIT 11	02SEP2020	11:47	5.45629352811	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35	2.03446916936	Double Read
					VISIT 6	26JAN2016	12:53	2.04820112112	Double Read
					VISIT 7	04AUG2016	13:49	7.47409546458	Double Read
					VISIT 8	19JUL2017	13:03	10.0702089349	Double Read
					VISIT 11	02SEP2020	11:47	11.259677255	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0220 Age=44 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35	14233.0	Double Read
					VISIT 6	26JAN2016	12:53	15134.0	Double Read
					VISIT 7	04AUG2016	13:49	13392.5	Double Read
					VISIT 8	19JUL2017	13:03	14076.5	Double Read
					VISIT 11	02SEP2020	11:47	13574.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	12AUG2015	10:50		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0220 Age=44 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 4	29SEP2015	11:35	14787.0	Double Read
					VISIT 6	26JAN2016	12:53	14452.0	Double Read
					VISIT 7	04AUG2016	13:49	13386.5	Double Read
					VISIT 8	19JUL2017	13:03	12975.5	Double Read
					VISIT 11	02SEP2020	11:47	14177.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35	17043.5	Double Read
					VISIT 6	26JAN2016	12:53	17044.0	Double Read
					VISIT 7	04AUG2016	13:49	16454.0	Double Read
					VISIT 8	19JUL2017	13:03	17997.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	02SEP2020	11:47	16680.5	Double Read
					Baseline	12AUG2015	10:50		Double Read
					VISIT 4	29SEP2015	11:35		Double Read
					VISIT 6	26JAN2016	12:53		Double Read
					VISIT 7	04AUG2016	13:49		Double Read
					VISIT 8	19JUL2017	13:03		Double Read
					VISIT 11	02SEP2020	11:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0221 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	-	12:54	2	Double Read
					VISIT 3A	10DEC2015	11:23	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	-	12:54	3	Double Read
					VISIT 3A	10DEC2015	11:23	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	-	12:54	2	Double Read
					VISIT 3A	10DEC2015	11:23	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	-	12:54	Y	Double Read
					VISIT 3A	10DEC2015	11:23	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read
Fracture	4_5		General		Baseline	-	12:54	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0221 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Fracture	4_5		General		VISIT 3A	10DEC2015	11:23	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23	11.06	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23	10.44	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23	12.615	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	-	12:54	6.96546	Double Read
					VISIT 3A	10DEC2015	11:23	7.644075	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	-	12:54	7.29696	Double Read
					VISIT 3A	10DEC2015	11:23	5.635585	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	-	12:54	10.10449	Double Read
					VISIT 3A	10DEC2015	11:23	9.854365	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0221 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read
Normal lordotic LS	4_5		General		Baseline	-	12:54	Y	Double Read
					VISIT 3A	10DEC2015	11:23	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	-	12:54	0	Double Read
					VISIT 3A	10DEC2015	11:23	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	-	12:54	2	Double Read
					VISIT 3A	10DEC2015	11:23	1	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	-	12:54	0	Double Read
					VISIT 3A	10DEC2015	11:23	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0221 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read
Relevant scoliosis	4_5		General		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	-	12:54	N	Double Read
					VISIT 3A	10DEC2015	11:23	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23	90.09328	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23	73.2248	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0221 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23	75.3648	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0221 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	-	12:54	lower	Double Read
					VISIT 3A	10DEC2015	11:23	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	-	12:54	lower	Double Read
					VISIT 3A	10DEC2015	11:23	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0221 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23	9.90883641921	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23	2.48057754374	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23	4.96789536267	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0221 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23	6919.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23	7717.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23	12556.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	-	12:54		Double Read
					VISIT 3A	10DEC2015	11:23		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0222 Age=42 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	08SEP2015	12:06		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	08SEP2015	12:06	2	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	08SEP2015	12:06	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	08SEP2015	12:06		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	08SEP2015	12:06	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	08SEP2015	12:06	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	08SEP2015	12:06		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	08SEP2015	12:06	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	08SEP2015	12:06	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	08SEP2015	12:06	N	Double Read
Fracture	5_S		General		Baseline	08SEP2015	12:06	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	08SEP2015	12:06		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	08SEP2015	12:06		Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	08SEP2015	12:06		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0222 Age=42 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	08SEP2015	12:06		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	08SEP2015	12:06	9.96229	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	08SEP2015	12:06	13.1853	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	08SEP2015	12:06		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	08SEP2015	12:06	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	08SEP2015	12:06	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	08SEP2015	12:06		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	08SEP2015	12:06	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	08SEP2015	12:06	N	Double Read
Normal lordotic LS	5_S		General		Baseline	08SEP2015	12:06	N	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	08SEP2015	12:06		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	08SEP2015	12:06	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0222 Age=42 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	08SEP2015	12:06	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	08SEP2015	12:06		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	08SEP2015	12:06	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	08SEP2015	12:06	N	Double Read
Relevant scoliosis	5_S		General		Baseline	08SEP2015	12:06	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	08SEP2015	12:06		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	08SEP2015	12:06	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	08SEP2015	12:06	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	08SEP2015	12:06		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	08SEP2015	12:06		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	08SEP2015	12:06		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	08SEP2015	12:06		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	08SEP2015	12:06		Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	08SEP2015	12:06		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0222 Age=42 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	08SEP2015	12:06		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	08SEP2015	12:06		Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	08SEP2015	12:06		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	08SEP2015	12:06		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	08SEP2015	12:06		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	08SEP2015	12:06		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	08SEP2015	12:06		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	08SEP2015	12:06		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	08SEP2015	12:06		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	08SEP2015	12:06		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0222 Age=42 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	08SEP2015	12:06	higher	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	08SEP2015	12:06		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	08SEP2015	12:06		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	08SEP2015	12:06		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	08SEP2015	12:06		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	08SEP2015	12:06		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	08SEP2015	12:06		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	08SEP2015	12:06		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	08SEP2015	12:06		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	08SEP2015	12:06		Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	08SEP2015	12:06		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	08SEP2015	12:06		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0222 Age=42 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	08SEP2015	12:06		Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	08SEP2015	12:06		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	08SEP2015	12:06		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	08SEP2015	12:06		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	08SEP2015	12:06		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	08SEP2015	12:06		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	08SEP2015	12:06		Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	08SEP2015	12:06		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	08SEP2015	12:06		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	08SEP2015	12:06		Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	08SEP2015	12:06		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	28DEC2015	14:19	3	Double Read
					VISIT 3A	21MAR2016	17:02	3	Double Read
					VISIT 4	27APR2016	12:21	3	Double Read
					VISIT 6	24AUG2016	13:25	4	Double Read
					VISIT 7	15MAR2017	13:28	3	Double Read
					VISIT 8	07MAR2018	10:39	3	Double Read
					VISIT 11	03MAR2021	14:23	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	14:19	2	Double Read
					VISIT 3A	21MAR2016	17:02	3	Double Read
					VISIT 4	27APR2016	12:21	2	Double Read
					VISIT 6	24AUG2016	13:25	3	Double Read
					VISIT 7	15MAR2017	13:28	3	Double Read
					VISIT 8	07MAR2018	10:39	2	Double Read
					VISIT 11	03MAR2021	14:23	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	28DEC2015	14:19	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	21MAR2016	17:02	N	Double Read
					VISIT 4	27APR2016	12:21	N	Double Read
					VISIT 6	24AUG2016	13:25	N	Double Read
					VISIT 7	15MAR2017	13:28	N	Double Read
					VISIT 8	07MAR2018	10:39	N	Double Read
					VISIT 11	03MAR2021	14:23	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	14:19	N	Double Read
					VISIT 3A	21MAR2016	17:02	N	Double Read
					VISIT 4	27APR2016	12:21	N	Double Read
					VISIT 6	24AUG2016	13:25	N	Double Read
					VISIT 7	15MAR2017	13:28	N	Double Read
					VISIT 8	07MAR2018	10:39	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	03MAR2021	14:23	N	Double Read
					Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
					Baseline	28DEC2015	14:19	Y	Double Read
					VISIT 3A	21MAR2016	17:02	N	Double Read
					VISIT 4	27APR2016	12:21	Y	Double Read
					VISIT 6	24AUG2016	13:25	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	15MAR2017	13:28	Y	Double Read
					VISIT 8	07MAR2018	10:39	Y	Double Read
					VISIT 11	03MAR2021	14:23	Y	Double Read
					Baseline	28DEC2015	14:19	N	Double Read
					VISIT 3A	21MAR2016	17:02	N	Double Read
					VISIT 4	27APR2016	12:21	N	Double Read
					VISIT 6	24AUG2016	13:25	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	15MAR2017	13:28	N	Double Read
					VISIT 8	07MAR2018	10:39	N	Double Read
					VISIT 11	03MAR2021	14:23	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	28DEC2015	14:19	N	Double Read
					VISIT 3A	21MAR2016	17:02	N	Double Read
					VISIT 4	27APR2016	12:21	N	Double Read
					VISIT 6	24AUG2016	13:25	N	Double Read
					VISIT 7	15MAR2017	13:28	N	Double Read
					VISIT 8	07MAR2018	10:39	N	Double Read
					VISIT 11	03MAR2021	14:23	N	Double Read
Fracture	5_S		General		Baseline	28DEC2015	14:19	N	Double Read
					VISIT 3A	21MAR2016	17:02	N	Double Read
					VISIT 4	27APR2016	12:21	N	Double Read
					VISIT 6	24AUG2016	13:25	N	Double Read
					VISIT 7	15MAR2017	13:28	N	Double Read
					VISIT 8	07MAR2018	10:39	N	Double Read
					VISIT 11	03MAR2021	14:23	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	28DEC2015	14:19	14.2	Double Read
					VISIT 3A	21MAR2016	17:02	13.46	Double Read
					VISIT 4	27APR2016	12:21	13.945	Double Read
					VISIT 6	24AUG2016	13:25	13.125	Double Read
					VISIT 7	15MAR2017	13:28	13.845	Double Read
					VISIT 8	07MAR2018	10:39	13.645	Double Read
					VISIT 11	03MAR2021	14:23	13.325	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	28DEC2015	14:19	13.275	Double Read
					VISIT 3A	21MAR2016	17:02	14.41	Double Read
					VISIT 4	27APR2016	12:21	14.785	Double Read
					VISIT 6	24AUG2016	13:25	13.26	Double Read
					VISIT 7	15MAR2017	13:28	14.79	Double Read
					VISIT 8	07MAR2018	10:39	15.385	Double Read
					VISIT 11	03MAR2021	14:23	14.15	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	28DEC2015	14:19	8.328145	Double Read
					VISIT 3A	21MAR2016	17:02	8.81258	Double Read
					VISIT 4	27APR2016	12:21	9.212575	Double Read
					VISIT 6	24AUG2016	13:25	8.239165	Double Read
					VISIT 7	15MAR2017	13:28	9.022545	Double Read
					VISIT 8	07MAR2018	10:39	9.05227	Double Read
					VISIT 11	03MAR2021	14:23	8.40571	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	28DEC2015	14:19	10.4645	Double Read
					VISIT 3A	21MAR2016	17:02	10.79875	Double Read
					VISIT 4	27APR2016	12:21	10.799	Double Read
					VISIT 6	24AUG2016	13:25	11.2098	Double Read
					VISIT 7	15MAR2017	13:28	10.462	Double Read
					VISIT 8	07MAR2018	10:39	11.1332	Double Read
					VISIT 11	03MAR2021	14:23	10.4139	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	28DEC2015	14:19	N	Double Read
					VISIT 3A	21MAR2016	17:02	N	Double Read
					VISIT 4	27APR2016	12:21	N	Double Read
					VISIT 6	24AUG2016	13:25	N	Double Read
					VISIT 7	15MAR2017	13:28	N	Double Read
					VISIT 8	07MAR2018	10:39	N	Double Read
					VISIT 11	03MAR2021	14:23	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	14:19	N	Double Read
					VISIT 3A	21MAR2016	17:02	N	Double Read
					VISIT 4	27APR2016	12:21	N	Double Read
					VISIT 6	24AUG2016	13:25	N	Double Read
					VISIT 7	15MAR2017	13:28	N	Double Read
					VISIT 8	07MAR2018	10:39	N	Double Read
					VISIT 11	03MAR2021	14:23	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	28DEC2015	14:19	N	Double Read
					VISIT 3A	21MAR2016	17:02	N	Double Read
					VISIT 4	27APR2016	12:21	N	Double Read
					VISIT 6	24AUG2016	13:25	N	Double Read
					VISIT 7	15MAR2017	13:28	N	Double Read
					VISIT 8	07MAR2018	10:39	N	Double Read
					VISIT 11	03MAR2021	14:23	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	14:19	N	Double Read
					VISIT 3A	21MAR2016	17:02	N	Double Read
					VISIT 4	27APR2016	12:21	N	Double Read
					VISIT 6	24AUG2016	13:25	N	Double Read
					VISIT 7	15MAR2017	13:28	N	Double Read
					VISIT 8	07MAR2018	10:39	N	Double Read
					VISIT 11	03MAR2021	14:23	N	Double Read
Normal lordotic LS	5_S		General		Baseline	28DEC2015	14:19	Y	Double Read
					VISIT 3A	21MAR2016	17:02	Y	Double Read
					VISIT 4	27APR2016	12:21	Y	Double Read
					VISIT 6	24AUG2016	13:25	Y	Double Read
					VISIT 7	15MAR2017	13:28	Y	Double Read
					VISIT 8	07MAR2018	10:39	Y	Double Read
					VISIT 11	03MAR2021	14:23	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	28DEC2015	14:19	0	Double Read
					VISIT 3A	21MAR2016	17:02	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	27APR2016	12:21	0	Double Read
					VISIT 6	24AUG2016	13:25	0	Double Read
					VISIT 7	15MAR2017	13:28	0	Double Read
					VISIT 8	07MAR2018	10:39	0	Double Read
					VISIT 11	03MAR2021	14:23	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	14:19	0	Double Read
					VISIT 3A	21MAR2016	17:02	0	Double Read
					VISIT 4	27APR2016	12:21	0	Double Read
					VISIT 6	24AUG2016	13:25	0	Double Read
					VISIT 7	15MAR2017	13:28	0	Double Read
					VISIT 8	07MAR2018	10:39	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 11	03MAR2021	14:23	0	Double Read
					Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23	N	Double Read
					Baseline	28DEC2015	14:19	N	Double Read
					VISIT 3A	21MAR2016	17:02	N	Double Read
					VISIT 4	27APR2016	12:21	N	Double Read
					VISIT 6	24AUG2016	13:25	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	15MAR2017	13:28	N	Double Read
					VISIT 8	07MAR2018	10:39	N	Double Read
					VISIT 11	03MAR2021	14:23	N	Double Read
					Baseline	28DEC2015	14:19	N	Double Read
					VISIT 3A	21MAR2016	17:02	N	Double Read
					VISIT 4	27APR2016	12:21	N	Double Read
					VISIT 6	24AUG2016	13:25	N	Double Read
					VISIT 7	15MAR2017	13:28	N	Double Read
					VISIT 8	07MAR2018	10:39	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	07MAR2018	10:39	N	Double Read
					VISIT 11	03MAR2021	14:23	N	Double Read
Relevant scoliosis	5_S		General		Baseline	28DEC2015	14:19	N	Double Read
					VISIT 3A	21MAR2016	17:02	N	Double Read
					VISIT 4	27APR2016	12:21	N	Double Read
					VISIT 6	24AUG2016	13:25	N	Double Read
					VISIT 7	15MAR2017	13:28	N	Double Read
					VISIT 8	07MAR2018	10:39	N	Double Read
					VISIT 11	03MAR2021	14:23	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	28DEC2015	14:19	N	Double Read
					VISIT 3A	21MAR2016	17:02	N	Double Read
					VISIT 4	27APR2016	12:21	N	Double Read
					VISIT 6	24AUG2016	13:25	N	Double Read
					VISIT 7	15MAR2017	13:28	N	Double Read
					VISIT 8	07MAR2018	10:39	N	Double Read
					VISIT 11	03MAR2021	14:23	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	14:19	N	Double Read
					VISIT 3A	21MAR2016	17:02	N	Double Read
					VISIT 4	27APR2016	12:21	N	Double Read
					VISIT 6	24AUG2016	13:25	N	Double Read
					VISIT 7	15MAR2017	13:28	N	Double Read
					VISIT 8	07MAR2018	10:39	N	Double Read
					VISIT 11	03MAR2021	14:23	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	28DEC2015	14:19	57.58528	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	21MAR2016	17:02	56.25056	Double Read
					VISIT 4	27APR2016	12:21	55.33824	Double Read
					VISIT 6	24AUG2016	13:25	52.660976	Double Read
					VISIT 7	15MAR2017	13:28	59.71264	Double Read
					VISIT 8	07MAR2018	10:39	54.81792	Double Read
					VISIT 11	03MAR2021	14:23	64.54528	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	28DEC2015	14:19	78.58032	Double Read
					VISIT 3A	21MAR2016	17:02	72.0856	Double Read
					VISIT 4	27APR2016	12:21	68.9	Double Read
					VISIT 6	24AUG2016	13:25	75.94528	Double Read
					VISIT 7	15MAR2017	13:28	77.7992	Double Read
					VISIT 8	07MAR2018	10:39	73.588	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	03MAR2021	14:23	78.07472	Double Read
					VISIT 3A	21MAR2016	17:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 8	07MAR2018	10:39		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	03MAR2021	14:23		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	28DEC2015	14:19	lower	Double Read
					VISIT 3A	21MAR2016	17:02	lower	Double Read
					VISIT 4	27APR2016	12:21	equal	Double Read
					VISIT 6	24AUG2016	13:25	lower	Double Read
					VISIT 7	15MAR2017	13:28	lower	Double Read
					VISIT 8	07MAR2018	10:39	lower	Double Read
					VISIT 11	03MAR2021	14:23	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	28DEC2015	14:19	9.5464582979	Double Read
					VISIT 3A	21MAR2016	17:02	9.9465873959	Double Read
					VISIT 4	27APR2016	12:21	11.069590623	Double Read
					VISIT 6	24AUG2016	13:25	2.1403091557	Double Read
					VISIT 7	15MAR2017	13:28	10.716106675	Double Read
					VISIT 8	07MAR2018	10:39	7.6166808221	Double Read
					VISIT 11	03MAR2021	14:23	7.1524783421	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	28DEC2015	14:19	3.3643689485	Double Read
					VISIT 3A	21MAR2016	17:02	11.8659351113	Double Read
					VISIT 4	27APR2016	12:21	9.0453541702	Double Read
					VISIT 6	24AUG2016	13:25	9.19540003397	Double Read
					VISIT 7	15MAR2017	13:28	8.75374893834	Double Read
					VISIT 8	07MAR2018	10:39	8.36117547136	Double Read
					VISIT 11	03MAR2021	14:23	11.8481399694	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	28DEC2015	14:19	10764.0	Double Read
					VISIT 3A	21MAR2016	17:02	11631.0	Double Read
					VISIT 4	27APR2016	12:21	11544.0	Double Read
					VISIT 6	24AUG2016	13:25	10577.0	Double Read
					VISIT 7	15MAR2017	13:28	11414.5	Double Read
					VISIT 8	07MAR2018	10:39	11215.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0223 Age=57 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 11	03MAR2021	14:23	10558.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	28DEC2015	14:19	12621.0	Double Read
					VISIT 3A	21MAR2016	17:02	13816.0	Double Read
					VISIT 4	27APR2016	12:21	12772.5	Double Read
					VISIT 6	24AUG2016	13:25	13409.5	Double Read
					VISIT 7	15MAR2017	13:28	13596.5	Double Read
					VISIT 8	07MAR2018	10:39	14350.5	Double Read
					VISIT 11	03MAR2021	14:23	13785.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	28DEC2015	14:19		Double Read
					VISIT 3A	21MAR2016	17:02		Double Read
					VISIT 4	27APR2016	12:21		Double Read
					VISIT 6	24AUG2016	13:25		Double Read
					VISIT 7	15MAR2017	13:28		Double Read
					VISIT 8	07MAR2018	10:39		Double Read
					VISIT 11	03MAR2021	14:23		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0224 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	28DEC2015	15:08		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	28DEC2015	15:08	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	15:08	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	28DEC2015	15:08		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	28DEC2015	15:08	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	15:08	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	28DEC2015	15:08		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	28DEC2015	15:08	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	15:08	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	28DEC2015	15:08	N	Double Read
Fracture	5_S		General		Baseline	28DEC2015	15:08	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	28DEC2015	15:08		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	28DEC2015	15:08	14.3	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	28DEC2015	15:08	13.7	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0224 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	28DEC2015	15:08		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	28DEC2015	15:08	10.3622	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	28DEC2015	15:08	12.33	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	28DEC2015	15:08		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	28DEC2015	15:08	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	15:08	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	28DEC2015	15:08		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	28DEC2015	15:08	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	15:08	N	Double Read
Normal lordotic LS	5_S		General		Baseline	28DEC2015	15:08	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	28DEC2015	15:08		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	28DEC2015	15:08	1	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0224 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	15:08	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	28DEC2015	15:08		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	28DEC2015	15:08	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	15:08	N	Double Read
Relevant scoliosis	5_S		General		Baseline	28DEC2015	15:08	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	28DEC2015	15:08		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	28DEC2015	15:08	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	15:08	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	28DEC2015	15:08		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	28DEC2015	15:08		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	28DEC2015	15:08		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	28DEC2015	15:08		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	28DEC2015	15:08	67.8416	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	28DEC2015	15:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0224 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	28DEC2015	15:08		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	28DEC2015	15:08	88.05888	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	28DEC2015	15:08		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	28DEC2015	15:08		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	28DEC2015	15:08		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	15:08		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	28DEC2015	15:08		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	28DEC2015	15:08		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	15:08		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	28DEC2015	15:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0224 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	28DEC2015	15:08	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	15:08		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	28DEC2015	15:08		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	28DEC2015	15:08		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	28DEC2015	15:08		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	28DEC2015	15:08		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	28DEC2015	15:08		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	28DEC2015	15:08		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	28DEC2015	15:08		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	28DEC2015	15:08	5.24841854935	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	28DEC2015	15:08		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	28DEC2015	15:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=02/0224 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	28DEC2015	15:08	11.9245795821	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	28DEC2015	15:08		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	28DEC2015	15:08		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	28DEC2015	15:08		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	28DEC2015	15:08		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	28DEC2015	15:08		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	28DEC2015	15:08	12536.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	28DEC2015	15:08		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	28DEC2015	15:08		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	28DEC2015	15:08	14324.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	28DEC2015	15:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=04/0401 Age=39 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S	4_5	Central Disc		Baseline	25JUN2015	11:05	3	Double Read
					VISIT 4	10AUG2015	8:59	3	Double Read
					VISIT 6	16DEC2015	8:43	3	Double Read
					VISIT 7	22JUN2016	9:05	3	Double Read
					VISIT 8	05JUL2017	8:37	3	Double Read
					UNSCHEDULED	25JUL2018	8:55	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	25JUN2015	11:05	3	Double Read
					VISIT 4	10AUG2015	8:59	2	Double Read
					VISIT 6	16DEC2015	8:43	3	Double Read
					VISIT 7	22JUN2016	9:05	3	Double Read
					VISIT 8	05JUL2017	8:37	3	Double Read
					UNSCHEDULED	25JUL2018	8:55	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S	4_5	Central Disc		Baseline	25JUN2015	11:05	N	Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43	N	Double Read
					VISIT 7	22JUN2016	9:05	N	Double Read
					VISIT 8	05JUL2017	8:37	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=04/0401 Age=39 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S	4_5	Central Disc		UNSCHEDULED	25JUL2018	8:55	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	25JUN2015	11:05	N	Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43	N	Double Read
					VISIT 7	22JUN2016	9:05	N	Double Read
					VISIT 8	05JUL2017	8:37	N	Double Read
					UNSCHEDULED	25JUL2018	8:55	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
Dorsal disc extrusion (Central Disc)	5_S	4_5	Central Disc		Baseline	25JUN2015	11:05	Y	Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43	N	Double Read
					VISIT 7	22JUN2016	9:05	N	Double Read
					VISIT 8	05JUL2017	8:37	Y	Double Read
					UNSCHEDULED	25JUL2018	8:55	Y	Double Read
Dorsal disc extrusion (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	25JUN2015	11:05	Y	Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43	N	Double Read
					VISIT 7	22JUN2016	9:05	Y	Double Read
					VISIT 8	05JUL2017	8:37	Y	Double Read
					UNSCHEDULED	25JUL2018	8:55	Y	Double Read
Extradiscal fluid collection	5_S	4_5	General		Baseline	25JUN2015	11:05	N	Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43	N	Double Read
					VISIT 7	22JUN2016	9:05	N	Double Read
					VISIT 8	05JUL2017	8:37	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=04/0401 Age=39 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S	4_5	General		UNSCHEDULED	25JUL2018	8:55	N	Double Read
Fracture	5_S	4_5	General		Baseline	25JUN2015	11:05	N	Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43	N	Double Read
					VISIT 7	22JUN2016	9:05	N	Double Read
					VISIT 8	05JUL2017	8:37	N	Double Read
					UNSCHEDULED	25JUL2018	8:55	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	25JUN2015	11:05	16.29	Double Read
					VISIT 4	10AUG2015	8:59	17.665	Double Read
					VISIT 6	16DEC2015	8:43	17.215	Double Read
					VISIT 7	22JUN2016	9:05	17.08	Double Read
					VISIT 8	05JUL2017	8:37	16.535	Double Read
					UNSCHEDULED	25JUL2018	8:55	16.765	Double Read
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	25JUN2015	11:05	16.58	Double Read
					VISIT 4	10AUG2015	8:59	17.265	Double Read
					VISIT 6	16DEC2015	8:43	18.555	Double Read
					VISIT 7	22JUN2016	9:05	18.1	Double Read
					VISIT 8	05JUL2017	8:37	18.16	Double Read
					UNSCHEDULED	25JUL2018	8:55	17.68	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=04/0401 Age=39 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	25JUN2015	11:05	10.14106	Double Read
					VISIT 4	10AUG2015	8:59	10.00835	Double Read
					VISIT 6	16DEC2015	8:43	9.22114	Double Read
					VISIT 7	22JUN2016	9:05	9.653775	Double Read
					VISIT 8	05JUL2017	8:37	9.516745	Double Read
					UNSCHEDULED	25JUL2018	8:55	9.195295	Double Read
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	25JUN2015	11:05	12.12575	Double Read
					VISIT 4	10AUG2015	8:59	12.39505	Double Read
					VISIT 6	16DEC2015	8:43	11.73065	Double Read
					VISIT 7	22JUN2016	9:05	11.90745	Double Read
					VISIT 8	05JUL2017	8:37	12.0132	Double Read
					UNSCHEDULED	25JUL2018	8:55	11.29755	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S	4_5	Central Disc		Baseline	25JUN2015	11:05	N	Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43	N	Double Read
					VISIT 7	22JUN2016	9:05	N	Double Read
					VISIT 8	05JUL2017	8:37	N	Double Read
					UNSCHEDULED	25JUL2018	8:55	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=04/0401 Age=39 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	25JUN2015	11:05	N	Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43	N	Double Read
					VISIT 7	22JUN2016	9:05	N	Double Read
					VISIT 8	05JUL2017	8:37	N	Double Read
					UNSCHEDULED	25JUL2018	8:55	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S	4_5	Central Disc		Baseline	25JUN2015	11:05	N	Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43	N	Double Read
					VISIT 7	22JUN2016	9:05	N	Double Read
					VISIT 8	05JUL2017	8:37	N	Double Read
					UNSCHEDULED	25JUL2018	8:55	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	25JUN2015	11:05	N	Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43	N	Double Read
					VISIT 7	22JUN2016	9:05	N	Double Read
					VISIT 8	05JUL2017	8:37	N	Double Read
					UNSCHEDULED	25JUL2018	8:55	N	Double Read
Normal lordotic LS	5_S	4_5	General		Baseline	25JUN2015	11:05	Y	Double Read
					VISIT 4	10AUG2015	8:59	Y	Double Read
					VISIT 6	16DEC2015	8:43	Y	Double Read
					VISIT 7	22JUN2016	9:05	Y	Double Read
					VISIT 8	05JUL2017	8:37	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=04/0401 Age=39 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	5_S	4_5	General		UNSCHEDULED	25JUL2018	8:55	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59	0	Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S	4_5	Central Disc		Baseline	25JUN2015	11:05	0	Double Read
					VISIT 4	10AUG2015	8:59	0	Double Read
					VISIT 6	16DEC2015	8:43	0	Double Read
					VISIT 7	22JUN2016	9:05	0	Double Read
					VISIT 8	05JUL2017	8:37	0	Double Read
					UNSCHEDULED	25JUL2018	8:55	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	25JUN2015	11:05	0	Double Read
					VISIT 4	10AUG2015	8:59	0	Double Read
					VISIT 6	16DEC2015	8:43	0	Double Read
					VISIT 7	22JUN2016	9:05	0	Double Read
					VISIT 8	05JUL2017	8:37	0	Double Read
					UNSCHEDULED	25JUL2018	8:55	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
Protruding osteophyte (Central Disc)	5_S	4_5	Central Disc		Baseline	25JUN2015	11:05	N	Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43	N	Double Read
					VISIT 7	22JUN2016	9:05	N	Double Read
					VISIT 8	05JUL2017	8:37	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=04/0401 Age=39 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S	4_5	Central Disc		UNSCHEDULED	25JUL2018	8:55	N	Double Read
Protruding osteophyte (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	25JUN2015	11:05	N	Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43	N	Double Read
					VISIT 7	22JUN2016	9:05	N	Double Read
					VISIT 8	05JUL2017	8:37	N	Double Read
					UNSCHEDULED	25JUL2018	8:55	N	Double Read
Relevant scoliosis	5_S	4_5	General		Baseline	25JUN2015	11:05	N	Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43	N	Double Read
					VISIT 7	22JUN2016	9:05	N	Double Read
					VISIT 8	05JUL2017	8:37	N	Double Read
					UNSCHEDULED	25JUL2018	8:55	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S	4_5	Central Disc		Baseline	25JUN2015	11:05	N	Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43	N	Double Read
					VISIT 7	22JUN2016	9:05	N	Double Read
					VISIT 8	05JUL2017	8:37	N	Double Read
					UNSCHEDULED	25JUL2018	8:55	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	25JUN2015	11:05	N	Double Read
					VISIT 4	10AUG2015	8:59	N	Double Read
					VISIT 6	16DEC2015	8:43	N	Double Read
					VISIT 7	22JUN2016	9:05	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=04/0401 Age=39 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 8	05JUL2017	8:37	N	Double Read
					UNSCHEDULED	25JUL2018	8:55	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	25JUN2015	11:05	69.32512	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=04/0401 Age=39 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S	4_5	Central Disc		Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=04/0401 Age=39 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	25JUN2015	11:05	equal	Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	25JUN2015	11:05	lower	Double Read
					VISIT 4	10AUG2015	8:59	equal	Double Read
					VISIT 6	16DEC2015	8:43	lower	Double Read
					VISIT 7	22JUN2016	9:05	lower	Double Read
					VISIT 8	05JUL2017	8:37	lower	Double Read
					UNSCHEDULED	25JUL2018	8:55	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=04/0401 Age=39 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	25JUN2015	11:05	lower	Double Read
					VISIT 4	10AUG2015	8:59	lower	Double Read
					VISIT 6	16DEC2015	8:43	lower	Double Read
					VISIT 7	22JUN2016	9:05	equal	Double Read
					VISIT 8	05JUL2017	8:37	lower	Double Read
					UNSCHEDULED	25JUL2018	8:55	lower	Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S	4_5	Central Disc		Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=04/0401 Age=39 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	25JUN2015	11:05	8.4998267368	Double Read
					VISIT 4	10AUG2015	8:59	8.6657312722	Double Read
					VISIT 6	16DEC2015	8:43	3.861117717	Double Read
					VISIT 7	22JUN2016	9:05	7.6439612705	Double Read
					VISIT 8	05JUL2017	8:37	7.7050314251	Double Read
								8	

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=04/0401 Age=39 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	UNSCHEDULED	25JUL2018	8:55	7.16095124851	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	25JUN2015	11:05	12.289532869	Double Read
					VISIT 4	10AUG2015	8:59	7.79684049601	Double Read
					VISIT 6	16DEC2015	8:43	10.3335009342	Double Read
					VISIT 7	22JUN2016	9:05	3.16752845253	Double Read
					VISIT 8	05JUL2017	8:37	9.52580941056	Double Read
					UNSCHEDULED	25JUL2018	8:55	11.3158960422	Double Read
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=04/0401 Age=39 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	UNSCHEDULED	25JUL2018	8:55		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	UNSCHEDULED	25JUL2018	8:55		Double Read
					Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
					Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
					Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55		Double Read
					Baseline	25JUN2015	11:05	15884.5	Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	VISIT 4	10AUG2015	8:59	16858.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=04/0401 Age=39 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	VISIT 6	16DEC2015	8:43	15604.0	Double Read
					VISIT 7	22JUN2016	9:05	17157.5	Double Read
					VISIT 8	05JUL2017	8:37	14637.5	Double Read
					UNSCHEDULED	25JUL2018	8:55	15334.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	25JUN2015	11:05	18969.0	Double Read
					VISIT 4	10AUG2015	8:59	18773.5	Double Read
					VISIT 6	16DEC2015	8:43	18223.0	Double Read
					VISIT 7	22JUN2016	9:05	19933.0	Double Read
					VISIT 8	05JUL2017	8:37	17888.5	Double Read
Volume (mm^3) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	25JUN2015	11:05		Double Read
					VISIT 4	10AUG2015	8:59		Double Read
					VISIT 6	16DEC2015	8:43		Double Read
					VISIT 7	22JUN2016	9:05		Double Read
					VISIT 8	05JUL2017	8:37		Double Read
					UNSCHEDULED	25JUL2018	8:55	19042.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	3_4		Caudal Disc		Baseline	22JUL2013	14:08	3	Double Read
					VISIT 3A	04NOV2013	15:49	3	Double Read
					VISIT 3K	07NOV2013	14:35	4	Single Read
					VISIT 4	18DEC2013	11:37	3	Double Read
					VISIT 5	12FEB2014	13:20	3	Double Read
					VISIT 6	22APR2014	9:12	3	Double Read
					VISIT 7	23OCT2014	9:29	3	Double Read
					VISIT 8	18NOV2015	14:23	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	3_4		Central Disc		Baseline	22JUL2013	14:08	2	Double Read
					VISIT 3A	04NOV2013	15:49	2	Double Read
					VISIT 3K	07NOV2013	14:35	3	Single Read
					VISIT 4	18DEC2013	11:37	2	Double Read
					VISIT 5	12FEB2014	13:20	3	Double Read
					VISIT 6	22APR2014	9:12	2	Double Read
					VISIT 7	23OCT2014	9:29	3	Double Read
					VISIT 8	18NOV2015	14:23	2	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	22JUL2013	14:08	3	Double Read
					VISIT 3A	04NOV2013	15:49	3	Double Read
					VISIT 3K	07NOV2013	14:35	4	Single Read
					VISIT 4	18DEC2013	11:37	3	Double Read
					VISIT 5	12FEB2014	13:20	3	Double Read
					VISIT 6	22APR2014	9:12	3	Double Read
					VISIT 7	23OCT2014	9:29	3	Double Read
					VISIT 8	18NOV2015	14:23	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	3_4		Caudal Disc		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	3_4		Caudal Disc		VISIT 8	18NOV2015	14:23	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	3_4		Central Disc		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
Dorsal disc extrusion (Caudal Disc)	3_4		Caudal Disc		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
Dorsal disc extrusion (Central Disc)	3_4		Central Disc		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Central Disc)	3_4		Central Disc		VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
Extradiscal fluid collection	3_4		General		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
Fracture	3_4		General		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	22JUL2013	14:08	13.145	Double Read
					VISIT 3A	04NOV2013	15:49	12.62	Double Read
					VISIT 3K	07NOV2013	14:35	12.21	Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20	13.705	Double Read
					VISIT 6	22APR2014	9:12	12.97	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	VISIT 7	23OCT2014	9:29	13.5	Double Read
					VISIT 8	18NOV2015	14:23	13.03	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	22JUL2013	14:08	12.925	Double Read
					VISIT 3A	04NOV2013	15:49	12.85	Double Read
					VISIT 3K	07NOV2013	14:35	12.04	Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20	13.565	Double Read
					VISIT 6	22APR2014	9:12	12.865	Double Read
					VISIT 7	23OCT2014	9:29	14.355	Double Read
					VISIT 8	18NOV2015	14:23	12.515	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	22JUL2013	14:08	11.615	Double Read
					VISIT 3A	04NOV2013	15:49	11.315	Double Read
					VISIT 3K	07NOV2013	14:35	11.46	Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20	11.75	Double Read
					VISIT 6	22APR2014	9:12	11.87	Double Read
					VISIT 7	23OCT2014	9:29	12.375	Double Read
					VISIT 8	18NOV2015	14:23	11.72	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	22JUL2013	14:08	10.18501	Double Read
					VISIT 3A	04NOV2013	15:49	10.59725	Double Read
					VISIT 3K	07NOV2013	14:35	10.5113	Single Read
					VISIT 4	18DEC2013	11:37	10.85045	Double Read
					VISIT 5	12FEB2014	13:20	10.6645	Double Read
					VISIT 6	22APR2014	9:12	10.44008	Double Read
					VISIT 7	23OCT2014	9:29	9.989625	Double Read
					VISIT 8	18NOV2015	14:23	11.2219	Double Read
Height manual (mm) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	22JUL2013	14:08	10.104025	Double Read
					VISIT 3A	04NOV2013	15:49	10.4837	Double Read
					VISIT 3K	07NOV2013	14:35	10.3723	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	VISIT 4	18DEC2013	11:37	10.96215	Double Read
					VISIT 5	12FEB2014	13:20	10.4365	Double Read
					VISIT 6	22APR2014	9:12	11.06165	Double Read
					VISIT 7	23OCT2014	9:29	10.3771	Double Read
					VISIT 8	18NOV2015	14:23	11.0614	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	22JUL2013	14:08	8.8903	Double Read
					VISIT 3A	04NOV2013	15:49	9.32655	Double Read
					VISIT 3K	07NOV2013	14:35	9.01538	Single Read
					VISIT 4	18DEC2013	11:37	9.22987	Double Read
					VISIT 5	12FEB2014	13:20	8.583745	Double Read
					VISIT 6	22APR2014	9:12	9.93242	Double Read
					VISIT 7	23OCT2014	9:29	9.047705	Double Read
					VISIT 8	18NOV2015	14:23	9.147625	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	3_4		Caudal Disc		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	3_4		Central Disc		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	3_4		Caudal Disc		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	3_4		Central Disc		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
Normal lordotic LS	3_4		General		Baseline	22JUL2013	14:08	Y	Double Read
					VISIT 3A	04NOV2013	15:49	Y	Double Read
					VISIT 3K	07NOV2013	14:35	Y	Single Read
					VISIT 4	18DEC2013	11:37	Y	Double Read
					VISIT 5	12FEB2014	13:20	Y	Double Read
					VISIT 6	22APR2014	9:12	Y	Double Read
					VISIT 7	23OCT2014	9:29	Y	Double Read
					VISIT 8	18NOV2015	14:23	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	3_4		Caudal Disc		Baseline	22JUL2013	14:08	0	Double Read
					VISIT 3A	04NOV2013	15:49	0	Double Read
					VISIT 3K	07NOV2013	14:35	0	Single Read
					VISIT 4	18DEC2013	11:37	0	Double Read
					VISIT 5	12FEB2014	13:20	0	Double Read
					VISIT 6	22APR2014	9:12	0	Double Read
					VISIT 7	23OCT2014	9:29	0	Double Read
					VISIT 8	18NOV2015	14:23	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	3_4		Central Disc		Baseline	22JUL2013	14:08	0	Double Read
					VISIT 3A	04NOV2013	15:49	0	Double Read
					VISIT 3K	07NOV2013	14:35	0	Single Read
					VISIT 4	18DEC2013	11:37	0	Double Read
					VISIT 5	12FEB2014	13:20	0	Double Read
					VISIT 6	22APR2014	9:12	0	Double Read
					VISIT 7	23OCT2014	9:29	0	Double Read
					VISIT 8	18NOV2015	14:23	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	22JUL2013	14:08	0	Double Read
					VISIT 3A	04NOV2013	15:49	0	Double Read
					VISIT 3K	07NOV2013	14:35	0	Single Read
					VISIT 4	18DEC2013	11:37	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		VISIT 5	12FEB2014	13:20	0	Double Read
					VISIT 6	22APR2014	9:12	0	Double Read
					VISIT 7	23OCT2014	9:29	0	Double Read
					VISIT 8	18NOV2015	14:23	0	Double Read
Protruding osteophyte (Caudal Disc)	3_4		Caudal Disc		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
Protruding osteophyte (Central Disc)	3_4		Central Disc		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
Relevant scoliosis	3_4		General		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Relevant scoliosis	3_4		General		VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	3_4		Caudal Disc		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	3_4		Central Disc		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	22JUL2013	14:08	N	Double Read
					VISIT 3A	04NOV2013	15:49	N	Double Read
					VISIT 3K	07NOV2013	14:35	N	Single Read
					VISIT 4	18DEC2013	11:37	N	Double Read
					VISIT 5	12FEB2014	13:20	N	Double Read
					VISIT 6	22APR2014	9:12	N	Double Read
					VISIT 7	23OCT2014	9:29	N	Double Read
					VISIT 8	18NOV2015	14:23	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	22JUL2013	14:08	88.23728	Double Read
					VISIT 3A	04NOV2013	15:49	93.21904	Double Read
					VISIT 3K	07NOV2013	14:35	86.51424	Single Read
					VISIT 4	18DEC2013	11:37	89.88976	Double Read
					VISIT 5	12FEB2014	13:20	100.244	Double Read
					VISIT 6	22APR2014	9:12	97.91376	Double Read
					VISIT 7	23OCT2014	9:29	64.02704	Double Read
					VISIT 8	18NOV2015	14:23	68.30016	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35	121.49536	Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	22JUL2013	14:08	96.9968	Double Read
					VISIT 3A	04NOV2013	15:49	94.43632	Double Read
					VISIT 3K	07NOV2013	14:35	105.53568	Single Read
					VISIT 4	18DEC2013	11:37	94.77936	Double Read
					VISIT 5	12FEB2014	13:20	98.41376	Double Read
					VISIT 6	22APR2014	9:12	98.45648	Double Read
					VISIT 7	23OCT2014	9:29	69.48416	Double Read
					VISIT 8	18NOV2015	14:23	75.61312	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35	102.99264	Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	22JUL2013	14:08	91.92432	Double Read
					VISIT 3A	04NOV2013	15:49	102.50064	Double Read
					VISIT 3K	07NOV2013	14:35	91.00544	Single Read
					VISIT 4	18DEC2013	11:37	99.46688	Double Read
					VISIT 5	12FEB2014	13:20	94.50288	Double Read
					VISIT 6	22APR2014	9:12	100.87248	Double Read
					VISIT 7	23OCT2014	9:29	59.40352	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	VISIT 8	18NOV2015	14:23	66.66944	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	3_4		Caudal Disc		Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49	equal	Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	3_4		Central Disc		Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49	higher	Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	22JUL2013	14:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35	equal	Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	3_4		Caudal Disc		Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	3_4		Central Disc		Baseline	22JUL2013	14:08	higher	Double Read
					VISIT 3A	04NOV2013	15:49	higher	Double Read
					VISIT 3K	07NOV2013	14:35	higher	Single Read
					VISIT 4	18DEC2013	11:37	higher	Double Read
					VISIT 5	12FEB2014	13:20	equal	Double Read
					VISIT 6	22APR2014	9:12	higher	Double Read
					VISIT 7	23OCT2014	9:29	higher	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	3_4		Caudal Disc		Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	3_4		Central Disc		Baseline	22JUL2013	14:08	higher	Double Read
					VISIT 3A	04NOV2013	15:49	higher	Double Read
					VISIT 3K	07NOV2013	14:35	higher	Single Read
					VISIT 4	18DEC2013	11:37	higher	Double Read
					VISIT 5	12FEB2014	13:20	equal	Double Read
					VISIT 6	22APR2014	9:12	higher	Double Read
					VISIT 7	23OCT2014	9:29	higher	Double Read
					VISIT 8	18NOV2015	14:23	higher	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		VISIT 8	18NOV2015	14:23		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	3_4		Caudal Disc		Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49	equal	Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	3_4		Central Disc		Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49	higher	Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49	equal	Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	22JUL2013	14:08	16.2873449974	Double Read
					VISIT 3A	04NOV2013	15:49	19.5115338882	Double Read
					VISIT 3K	07NOV2013	14:35	14.3402072363	Single Read
					VISIT 4	18DEC2013	11:37	20.8254119246	Double Read
					VISIT 5	12FEB2014	13:20	19.5408187532	Double Read
					VISIT 6	22APR2014	9:12	20.0778664854	Double Read
					VISIT 7	23OCT2014	9:29	8.7969899779	Double Read
					VISIT 8	18NOV2015	14:23	3.43506030236	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35	20.915916426	Single Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
T2_error (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	22JUL2013	14:08	16.295430609	Double Read
					VISIT 3A	04NOV2013	15:49	14.011075250	Double Read
					VISIT 3K	07NOV2013	14:35	12.683308985	Single Read
					VISIT 4	18DEC2013	11:37	19.202310175	Double Read
					VISIT 5	12FEB2014	13:20	21.722099541	Double Read
					VISIT 6	22APR2014	9:12	12.912423985	Double Read
					VISIT 7	23OCT2014	9:29	6.1670732121	Double Read
					VISIT 8	18NOV2015	14:23	12.305833191	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35	11.664114149	Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	22JUL2013	14:08	22.205673517	Double Read
					VISIT 3A	04NOV2013	15:49	28.528962119	Double Read
					VISIT 3K	07NOV2013	14:35	17.543332767	Single Read
					VISIT 4	18DEC2013	11:37	14.007711907	Double Read
					VISIT 5	12FEB2014	13:20	14.102802785	Double Read
					VISIT 6	22APR2014	9:12	18.823441481	Double Read
					VISIT 7	23OCT2014	9:29	11.573521318	Double Read
					VISIT 8	18NOV2015	14:23	2.7178528962	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	22JUL2013	14:08	14253.5	Double Read
					VISIT 3A	04NOV2013	15:49	13168.5	Double Read
					VISIT 3K	07NOV2013	14:35	11630	Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20	14883.0	Double Read
					VISIT 6	22APR2014	9:12	13718.0	Double Read
					VISIT 7	23OCT2014	9:29	12294.0	Double Read
					VISIT 8	18NOV2015	14:23	13040.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35	5075	Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	22JUL2013	14:08	13974.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	VISIT 3A	04NOV2013	15:49	13659.0	Double Read
					VISIT 3K	07NOV2013	14:35	12784	Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20	13931.0	Double Read
					VISIT 6	22APR2014	9:12	13210.0	Double Read
					VISIT 7	23OCT2014	9:29	13675.5	Double Read
					VISIT 8	18NOV2015	14:23	13185.0	Double Read
Volume (mm ³) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35	7709	Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
Volume (mm ³) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
Volume (mm ³) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	22JUL2013	14:08	11618.5	Double Read
					VISIT 3A	04NOV2013	15:49	11932.5	Double Read
					VISIT 3K	07NOV2013	14:35	11539	Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20	12992.5	Double Read
					VISIT 6	22APR2014	9:12	12163.0	Double Read
					VISIT 7	23OCT2014	9:29	11383.0	Double Read
					VISIT 8	18NOV2015	14:23	11331.0	Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0602 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	22JUL2013	14:08		Double Read
					VISIT 3A	04NOV2013	15:49		Double Read
					VISIT 3K	07NOV2013	14:35		Single Read
					VISIT 4	18DEC2013	11:37		Double Read
					VISIT 5	12FEB2014	13:20		Double Read
					VISIT 6	22APR2014	9:12		Double Read
					VISIT 7	23OCT2014	9:29		Double Read
					VISIT 8	18NOV2015	14:23		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0604 Age=34 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	27OCT2014	10:21		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	27OCT2014	10:21	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27OCT2014	10:21	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	27OCT2014	10:21		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	27OCT2014	10:21	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27OCT2014	10:21	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	27OCT2014	10:21		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	27OCT2014	10:21	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27OCT2014	10:21	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	27OCT2014	10:21	N	Double Read
Fracture	5_S		General		Baseline	27OCT2014	10:21	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	27OCT2014	10:21		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	27OCT2014	10:21	12.915	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	27OCT2014	10:21	14.975	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0604 Age=34 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	27OCT2014	10:21		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	27OCT2014	10:21	8.259835	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	27OCT2014	10:21	11.78675	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	27OCT2014	10:21		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	27OCT2014	10:21	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27OCT2014	10:21	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	27OCT2014	10:21		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	27OCT2014	10:21	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27OCT2014	10:21	N	Double Read
Normal lordotic LS	5_S		General		Baseline	27OCT2014	10:21	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	27OCT2014	10:21		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	27OCT2014	10:21	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0604 Age=34 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27OCT2014	10:21	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	27OCT2014	10:21		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	27OCT2014	10:21	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27OCT2014	10:21	N	Double Read
Relevant scoliosis	5_S		General		Baseline	27OCT2014	10:21	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	27OCT2014	10:21		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	27OCT2014	10:21	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	27OCT2014	10:21	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	27OCT2014	10:21		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	27OCT2014	10:21		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	27OCT2014	10:21		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	27OCT2014	10:21		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	27OCT2014	10:21	80.64016	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	27OCT2014	10:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0604 Age=34 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	27OCT2014	10:21		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	27OCT2014	10:21	96.24752	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	27OCT2014	10:21		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	27OCT2014	10:21		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	27OCT2014	10:21		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	27OCT2014	10:21		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	27OCT2014	10:21		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	27OCT2014	10:21		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	27OCT2014	10:21		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	27OCT2014	10:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0604 Age=34 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	27OCT2014	10:21	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	27OCT2014	10:21		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	27OCT2014	10:21		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	27OCT2014	10:21		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	27OCT2014	10:21		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	27OCT2014	10:21		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	27OCT2014	10:21		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	27OCT2014	10:21		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	27OCT2014	10:21		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	27OCT2014	10:21	8.16906403941	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	27OCT2014	10:21		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	27OCT2014	10:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0604 Age=34 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	27OCT2014	10:21	11.8731849838	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	27OCT2014	10:21		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	27OCT2014	10:21		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	27OCT2014	10:21		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	27OCT2014	10:21		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	27OCT2014	10:21		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	27OCT2014	10:21	16772.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	27OCT2014	10:21		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	27OCT2014	10:21		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	27OCT2014	10:21	24707.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	27OCT2014	10:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0605 Age=51 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	11DEC2014	7:45		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	11DEC2014	7:45	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11DEC2014	7:45	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	11DEC2014	7:45		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	11DEC2014	7:45	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11DEC2014	7:45	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	11DEC2014	7:45		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	11DEC2014	7:45	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11DEC2014	7:45	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	11DEC2014	7:45	N	Double Read
Fracture	5_S		General		Baseline	11DEC2014	7:45	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11DEC2014	7:45		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11DEC2014	7:45	19.545	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11DEC2014	7:45	21.445	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0605 Age=51 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11DEC2014	7:45		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11DEC2014	7:45	8.94113	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11DEC2014	7:45	15.5743	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	11DEC2014	7:45		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	11DEC2014	7:45	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11DEC2014	7:45	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	11DEC2014	7:45		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	11DEC2014	7:45	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11DEC2014	7:45	N	Double Read
Normal lordotic LS	5_S		General		Baseline	11DEC2014	7:45	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	11DEC2014	7:45		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	11DEC2014	7:45	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0605 Age=51 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11DEC2014	7:45	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	11DEC2014	7:45		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	11DEC2014	7:45	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11DEC2014	7:45	N	Double Read
Relevant scoliosis	5_S		General		Baseline	11DEC2014	7:45	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	11DEC2014	7:45		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	11DEC2014	7:45	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11DEC2014	7:45	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	11DEC2014	7:45		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11DEC2014	7:45		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	11DEC2014	7:45		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	11DEC2014	7:45		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11DEC2014	7:45		Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	11DEC2014	7:45		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0605 Age=51 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11DEC2014	7:45		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11DEC2014	7:45		Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	11DEC2014	7:45		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	11DEC2014	7:45		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	11DEC2014	7:45		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11DEC2014	7:45		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	11DEC2014	7:45		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	11DEC2014	7:45		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11DEC2014	7:45		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	11DEC2014	7:45		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0605 Age=51 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	11DEC2014	7:45	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11DEC2014	7:45		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	11DEC2014	7:45		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	11DEC2014	7:45		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11DEC2014	7:45		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	11DEC2014	7:45		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11DEC2014	7:45		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	11DEC2014	7:45		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	11DEC2014	7:45		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11DEC2014	7:45		Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	11DEC2014	7:45		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11DEC2014	7:45		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0605 Age=51 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11DEC2014	7:45		Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	11DEC2014	7:45		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	11DEC2014	7:45		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11DEC2014	7:45		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	11DEC2014	7:45		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	11DEC2014	7:45		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11DEC2014	7:45	17947.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	11DEC2014	7:45		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11DEC2014	7:45		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11DEC2014	7:45	25693.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	11DEC2014	7:45		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirschmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
Disc degeneration grading (Pfirschmann) (Central Disc)	5_S		Central Disc		Baseline	15DEC2014	13:14	4	Double Read
					VISIT 4	10FEB2015	10:17	3	Double Read
					VISIT 6	03JUN2015	12:18	4	Double Read
					VISIT 7	03DEC2015	14:43	3	Double Read
					VISIT 8	24NOV2016	13:47	4	Double Read
					VISIT 11	03DEC2019	14:02	3	Double Read
Disc degeneration grading (Pfirschmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15DEC2014	13:14	2	Double Read
					VISIT 4	10FEB2015	10:17	2	Double Read
					VISIT 6	03JUN2015	12:18	2	Double Read
					VISIT 7	03DEC2015	14:43	2	Double Read
					VISIT 8	24NOV2016	13:47	2	Double Read
					VISIT 11	03DEC2019	14:02	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	15DEC2014	13:14	N	Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18	N	Double Read
					VISIT 7	03DEC2015	14:43	N	Double Read
					VISIT 8	24NOV2016	13:47	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 11	03DEC2019	14:02	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15DEC2014	13:14	N	Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18	N	Double Read
					VISIT 7	03DEC2015	14:43	N	Double Read
					VISIT 8	24NOV2016	13:47	N	Double Read
					VISIT 11	03DEC2019	14:02	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	15DEC2014	13:14	Y	Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18	Y	Double Read
					VISIT 7	03DEC2015	14:43	Y	Double Read
					VISIT 8	24NOV2016	13:47	N	Double Read
					VISIT 11	03DEC2019	14:02	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15DEC2014	13:14	N	Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18	N	Double Read
					VISIT 7	03DEC2015	14:43	N	Double Read
					VISIT 8	24NOV2016	13:47	N	Double Read
					VISIT 11	03DEC2019	14:02	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	15DEC2014	13:14	N	Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18	N	Double Read
					VISIT 7	03DEC2015	14:43	N	Double Read
					VISIT 8	24NOV2016	13:47	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 11	03DEC2019	14:02	N	Double Read
Fracture	5_S		General		Baseline	15DEC2014	13:14	N	Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18	N	Double Read
					VISIT 7	03DEC2015	14:43	N	Double Read
					VISIT 8	24NOV2016	13:47	N	Double Read
					VISIT 11	03DEC2019	14:02	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15DEC2014	13:14	14.135	Double Read
					VISIT 4	10FEB2015	10:17	16.855	Double Read
					VISIT 6	03JUN2015	12:18	14.805	Double Read
					VISIT 7	03DEC2015	14:43	14.24	Double Read
					VISIT 8	24NOV2016	13:47	14.865	Double Read
					VISIT 11	03DEC2019	14:02	16.83	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15DEC2014	13:14	14.23	Double Read
					VISIT 4	10FEB2015	10:17	16.26	Double Read
					VISIT 6	03JUN2015	12:18	15.105	Double Read
					VISIT 7	03DEC2015	14:43	15.17	Double Read
					VISIT 8	24NOV2016	13:47	14.925	Double Read
					VISIT 11	03DEC2019	14:02	16.11	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15DEC2014	13:14	8.849695	Double Read
					VISIT 4	10FEB2015	10:17	10.512	Double Read
					VISIT 6	03JUN2015	12:18	9.320945	Double Read
					VISIT 7	03DEC2015	14:43	9.686725	Double Read
					VISIT 8	24NOV2016	13:47	9.76445	Double Read
					VISIT 11	03DEC2019	14:02	10.32655	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15DEC2014	13:14	11.16195	Double Read
					VISIT 4	10FEB2015	10:17	12.20335	Double Read
					VISIT 6	03JUN2015	12:18	11.1522	Double Read
					VISIT 7	03DEC2015	14:43	11.8587	Double Read
					VISIT 8	24NOV2016	13:47	11.6467	Double Read
					VISIT 11	03DEC2019	14:02	11.14565	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	15DEC2014	13:14	N	Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18	N	Double Read
					VISIT 7	03DEC2015	14:43	N	Double Read
					VISIT 8	24NOV2016	13:47	N	Double Read
					VISIT 11	03DEC2019	14:02	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15DEC2014	13:14	N	Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18	N	Double Read
					VISIT 7	03DEC2015	14:43	N	Double Read
					VISIT 8	24NOV2016	13:47	N	Double Read
					VISIT 11	03DEC2019	14:02	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	15DEC2014	13:14	N	Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18	N	Double Read
					VISIT 7	03DEC2015	14:43	N	Double Read
					VISIT 8	24NOV2016	13:47	N	Double Read
					VISIT 11	03DEC2019	14:02	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15DEC2014	13:14	N	Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18	N	Double Read
					VISIT 7	03DEC2015	14:43	N	Double Read
					VISIT 8	24NOV2016	13:47	N	Double Read
					VISIT 11	03DEC2019	14:02	N	Double Read
Normal lordotic LS	5_S		General		Baseline	15DEC2014	13:14	Y	Double Read
					VISIT 4	10FEB2015	10:17	Y	Double Read
					VISIT 6	03JUN2015	12:18	Y	Double Read
					VISIT 7	03DEC2015	14:43	Y	Double Read
					VISIT 8	24NOV2016	13:47	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	5_S		General		VISIT 11	03DEC2019	14:02	N	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17	0	Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	15DEC2014	13:14	0	Double Read
					VISIT 4	10FEB2015	10:17	0	Double Read
					VISIT 6	03JUN2015	12:18	0	Double Read
					VISIT 7	03DEC2015	14:43	0	Double Read
					VISIT 8	24NOV2016	13:47	0	Double Read
					VISIT 11	03DEC2019	14:02	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15DEC2014	13:14	0	Double Read
					VISIT 4	10FEB2015	10:17	0	Double Read
					VISIT 6	03JUN2015	12:18	0	Double Read
					VISIT 7	03DEC2015	14:43	0	Double Read
					VISIT 8	24NOV2016	13:47	0	Double Read
					VISIT 11	03DEC2019	14:02	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	15DEC2014	13:14	N	Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18	N	Double Read
					VISIT 7	03DEC2015	14:43	N	Double Read
					VISIT 8	24NOV2016	13:47	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 11	03DEC2019	14:02	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15DEC2014	13:14	N	Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18	N	Double Read
					VISIT 7	03DEC2015	14:43	N	Double Read
					VISIT 8	24NOV2016	13:47	N	Double Read
					VISIT 11	03DEC2019	14:02	N	Double Read
Relevant scoliosis	5_S		General		Baseline	15DEC2014	13:14	N	Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18	N	Double Read
					VISIT 7	03DEC2015	14:43	N	Double Read
					VISIT 8	24NOV2016	13:47	N	Double Read
					VISIT 11	03DEC2019	14:02	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	15DEC2014	13:14	N	Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18	N	Double Read
					VISIT 7	03DEC2015	14:43	N	Double Read
					VISIT 8	24NOV2016	13:47	N	Double Read
					VISIT 11	03DEC2019	14:02	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15DEC2014	13:14	N	Double Read
					VISIT 4	10FEB2015	10:17	N	Double Read
					VISIT 6	03JUN2015	12:18	N	Double Read
					VISIT 7	03DEC2015	14:43	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	24NOV2016	13:47	N	Double Read
					VISIT 11	03DEC2019	14:02	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15DEC2014	13:14	57.30128	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 4	10FEB2015	10:17	58.99616	Double Read
					VISIT 6	03JUN2015	12:18	64.06512	Double Read
					VISIT 7	03DEC2015	14:43	63.29408	Double Read
					VISIT 8	24NOV2016	13:47	78.05376	Double Read
					VISIT 11	03DEC2019	14:02	71.23824	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15DEC2014	13:14	86.18768	Double Read
					VISIT 4	10FEB2015	10:17	92.7384	Double Read
					VISIT 6	03JUN2015	12:18	94.52368	Double Read
					VISIT 7	03DEC2015	14:43	88.23376	Double Read
					VISIT 8	24NOV2016	13:47	92.17008	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	03DEC2019	14:02	83.58048	Double Read
					Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	15DEC2014	13:14	lower	Double Read
					VISIT 4	10FEB2015	10:17	lower	Double Read
					VISIT 6	03JUN2015	12:18	lower	Double Read
					VISIT 7	03DEC2015	14:43	lower	Double Read
					VISIT 8	24NOV2016	13:47	lower	Double Read
					VISIT 11	03DEC2019	14:02	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15DEC2014	13:14	5.6662408697	Double Read
					VISIT 4	10FEB2015	10:17	9.6688160353	Double Read
					VISIT 6	03JUN2015	12:18	6.5851333446	Double Read
					VISIT 7	03DEC2015	14:43	4.6854696789	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	24NOV2016	13:47	22.4432818074	Double Read
					VISIT 11	03DEC2019	14:02	19.2326821811	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15DEC2014	13:14	7.15862748429	Double Read
					VISIT 4	10FEB2015	10:17	7.75720740616	Double Read
					VISIT 6	03JUN2015	12:18	6.315916426	Double Read
					VISIT 7	03DEC2015	14:43	5.80563275012	Double Read
					VISIT 8	24NOV2016	13:47	26.8820112112	Double Read
					VISIT 11	03DEC2019	14:02	26.5948021064	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15DEC2014	13:14	10914.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0606 Age=38 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 4	10FEB2015	10:17	12563.5	Double Read
					VISIT 6	03JUN2015	12:18	11665.5	Double Read
					VISIT 7	03DEC2015	14:43	12523.0	Double Read
					VISIT 8	24NOV2016	13:47	13554.0	Double Read
					VISIT 11	03DEC2019	14:02	12526.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15DEC2014	13:14	15397.5	Double Read
					VISIT 4	10FEB2015	10:17	16781.5	Double Read
					VISIT 6	03JUN2015	12:18	15948.0	Double Read
					VISIT 7	03DEC2015	14:43	16568.5	Double Read
					VISIT 8	24NOV2016	13:47	17570.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	03DEC2019	14:02	16555.5	Double Read
					Baseline	15DEC2014	13:14		Double Read
					VISIT 4	10FEB2015	10:17		Double Read
					VISIT 6	03JUN2015	12:18		Double Read
					VISIT 7	03DEC2015	14:43		Double Read
					VISIT 8	24NOV2016	13:47		Double Read
					VISIT 11	03DEC2019	14:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15	3	Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37	3	Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	19JAN2015	13:03	3	Double Read
					VISIT 3A	14APR2015	15:23	3	Double Read
					VISIT 4	01JUN2015	14:15	4	Double Read
					VISIT 6	06OCT2015	14:15	4	Double Read
					VISIT 7	05APR2016	14:37	4	Double Read
					VISIT 8	05APR2017	13:36	4	Double Read
					VISIT 11	16MAR2020	14:40	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	19JAN2015	13:03	3	Double Read
					VISIT 3A	14APR2015	15:23	3	Double Read
					VISIT 4	01JUN2015	14:15	4	Double Read
					VISIT 6	06OCT2015	14:15	4	Double Read
					VISIT 7	05APR2016	14:37	4	Double Read
					VISIT 8	05APR2017	13:36	4	Double Read
					VISIT 11	16MAR2020	14:40	4	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37	N	Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	19JAN2015	13:03	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	14APR2015	15:23	N	Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15	N	Double Read
					VISIT 7	05APR2016	14:37	N	Double Read
					VISIT 8	05APR2017	13:36	N	Double Read
					VISIT 11	16MAR2020	14:40	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23	N	Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15	N	Double Read
					VISIT 7	05APR2016	14:37	N	Double Read
					VISIT 8	05APR2017	13:36	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	16MAR2020	14:40	N	Double Read
					Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23	N	Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15	N	Double Read
					VISIT 7	05APR2016	14:37	N	Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	05APR2017	13:36	N	Double Read
					VISIT 11	16MAR2020	14:40	N	Double Read
					Baseline	19JAN2015	13:03	Y	Double Read
					VISIT 3A	14APR2015	15:23	Y	Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	05APR2016	14:37	Y	Double Read
					VISIT 8	05APR2017	13:36	Y	Double Read
					VISIT 11	16MAR2020	14:40	N	Double Read
					Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23	N	Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	05APR2016	14:37	N	Double Read
					VISIT 8	05APR2017	13:36	N	Double Read
					VISIT 11	16MAR2020	14:40	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23	N	Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15	N	Double Read
					VISIT 7	05APR2016	14:37	N	Double Read
					VISIT 8	05APR2017	13:36	N	Double Read
					VISIT 11	16MAR2020	14:40	N	Double Read
Fracture	5_S		General		Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23	N	Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15	N	Double Read
					VISIT 7	05APR2016	14:37	N	Double Read
					VISIT 8	05APR2017	13:36	N	Double Read
					VISIT 11	16MAR2020	14:40	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	19JAN2015	13:03	9.095	Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	19JAN2015	13:03	13.035	Double Read
					VISIT 3A	14APR2015	15:23	11.35	Double Read
					VISIT 4	01JUN2015	14:15	12.175	Double Read
					VISIT 6	06OCT2015	14:15	12.23	Double Read
					VISIT 7	05APR2016	14:37	12.99	Double Read
					VISIT 8	05APR2017	13:36	13.725	Double Read
					VISIT 11	16MAR2020	14:40	11.015	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	19JAN2015	13:03	12.79	Double Read
					VISIT 3A	14APR2015	15:23	12.355	Double Read
					VISIT 4	01JUN2015	14:15	11.885	Double Read
					VISIT 6	06OCT2015	14:15	11.42	Double Read
					VISIT 7	05APR2016	14:37	12.8	Double Read
					VISIT 8	05APR2017	13:36	12.085	Double Read
					VISIT 11	16MAR2020	14:40	11.815	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	19JAN2015	13:03	6.817385	Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	19JAN2015	13:03	8.92836	Double Read
					VISIT 3A	14APR2015	15:23	7.829775	Double Read
					VISIT 4	01JUN2015	14:15	7.74144	Double Read
					VISIT 6	06OCT2015	14:15	7.892565	Double Read
					VISIT 7	05APR2016	14:37	6.94049	Double Read
					VISIT 8	05APR2017	13:36	8.768685	Double Read
					VISIT 11	16MAR2020	14:40	6.56116	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	19JAN2015	13:03	8.36927	Double Read
					VISIT 3A	14APR2015	15:23	8.674685	Double Read
					VISIT 4	01JUN2015	14:15	8.683565	Double Read
					VISIT 6	06OCT2015	14:15	8.47157	Double Read
					VISIT 7	05APR2016	14:37	8.52813	Double Read
					VISIT 8	05APR2017	13:36	8.05452	Double Read
					VISIT 11	16MAR2020	14:40	8.70172	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37	N	Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23	N	Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15	N	Double Read
					VISIT 7	05APR2016	14:37	N	Double Read
					VISIT 8	05APR2017	13:36	N	Double Read
					VISIT 11	16MAR2020	14:40	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23	N	Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15	N	Double Read
					VISIT 7	05APR2016	14:37	N	Double Read
					VISIT 8	05APR2017	13:36	N	Double Read
					VISIT 11	16MAR2020	14:40	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37	N	Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23	N	Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15	N	Double Read
					VISIT 7	05APR2016	14:37	N	Double Read
					VISIT 8	05APR2017	13:36	N	Double Read
					VISIT 11	16MAR2020	14:40	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23	N	Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15	N	Double Read
					VISIT 7	05APR2016	14:37	N	Double Read
					VISIT 8	05APR2017	13:36	N	Double Read
					VISIT 11	16MAR2020	14:40	N	Double Read
Normal lordotic LS	5_S		General		Baseline	19JAN2015	13:03	Y	Double Read
					VISIT 3A	14APR2015	15:23	Y	Double Read
					VISIT 4	01JUN2015	14:15	Y	Double Read
					VISIT 6	06OCT2015	14:15	Y	Double Read
					VISIT 7	05APR2016	14:37	Y	Double Read
					VISIT 8	05APR2017	13:36	Y	Double Read
					VISIT 11	16MAR2020	14:40	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	19JAN2015	13:03	0	Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15	0	Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37	0	Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	19JAN2015	13:03	2	Double Read
					VISIT 3A	14APR2015	15:23	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	01JUN2015	14:15	2	Double Read
					VISIT 6	06OCT2015	14:15	0	Double Read
					VISIT 7	05APR2016	14:37	2	Double Read
					VISIT 8	05APR2017	13:36	2	Double Read
					VISIT 11	16MAR2020	14:40	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	19JAN2015	13:03	0	Double Read
					VISIT 3A	14APR2015	15:23	0	Double Read
					VISIT 4	01JUN2015	14:15	0	Double Read
					VISIT 6	06OCT2015	14:15	0	Double Read
					VISIT 7	05APR2016	14:37	0	Double Read
					VISIT 8	05APR2017	13:36	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 11	16MAR2020	14:40	0	Double Read
					Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37	N	Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
					Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23	N	Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	05APR2016	14:37	N	Double Read
					VISIT 8	05APR2017	13:36	N	Double Read
					VISIT 11	16MAR2020	14:40	N	Double Read
					Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23	N	Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15	N	Double Read
					VISIT 7	05APR2016	14:37	N	Double Read
					VISIT 8	05APR2017	13:36	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	05APR2017	13:36	N	Double Read
					VISIT 11	16MAR2020	14:40	N	Double Read
Relevant scoliosis	5_S		General		Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23	N	Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15	N	Double Read
					VISIT 7	05APR2016	14:37	N	Double Read
					VISIT 8	05APR2017	13:36	N	Double Read
					VISIT 11	16MAR2020	14:40	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37	N	Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23	N	Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15	N	Double Read
					VISIT 7	05APR2016	14:37	N	Double Read
					VISIT 8	05APR2017	13:36	N	Double Read
					VISIT 11	16MAR2020	14:40	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	19JAN2015	13:03	N	Double Read
					VISIT 3A	14APR2015	15:23	N	Double Read
					VISIT 4	01JUN2015	14:15	N	Double Read
					VISIT 6	06OCT2015	14:15	N	Double Read
					VISIT 7	05APR2016	14:37	N	Double Read
					VISIT 8	05APR2017	13:36	N	Double Read
					VISIT 11	16MAR2020	14:40	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	19JAN2015	13:03	62.62784	Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	19JAN2015	13:03	68.45712	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	14APR2015	15:23	59.84176	Double Read
					VISIT 4	01JUN2015	14:15	64.39232	Double Read
					VISIT 6	06OCT2015	14:15	54.65552	Double Read
					VISIT 7	05APR2016	14:37	70.30464	Double Read
					VISIT 8	05APR2017	13:36	69.02496	Double Read
					VISIT 11	16MAR2020	14:40	71.75264	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	19JAN2015	13:03	63.0432	Double Read
					VISIT 3A	14APR2015	15:23	59.71488	Double Read
					VISIT 4	01JUN2015	14:15	62.5016	Double Read
					VISIT 6	06OCT2015	14:15	53.449424	Double Read
					VISIT 7	05APR2016	14:37	61.4456	Double Read
					VISIT 8	05APR2017	13:36	68.58928	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	16MAR2020	14:40	64.79664	Double Read
					VISIT 3A	14APR2015	15:23		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	19JAN2015	13:03	lower	Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15	lower	Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37	lower	Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	16MAR2020	14:40		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	19JAN2015	13:03	equal	Double Read
					VISIT 3A	14APR2015	15:23	equal	Double Read
					VISIT 4	01JUN2015	14:15	equal	Double Read
					VISIT 6	06OCT2015	14:15	equal	Double Read
					VISIT 7	05APR2016	14:37	equal	Double Read
					VISIT 8	05APR2017	13:36	equal	Double Read
					VISIT 11	16MAR2020	14:40	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	19JAN2015	13:03	4.55186682521	Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	19JAN2015	13:03	5.0912587056	Double Read
					VISIT 3A	14APR2015	15:23	7.4316290130	Double Read
					VISIT 4	01JUN2015	14:15	9.7527229488	Double Read
					VISIT 6	06OCT2015	14:15	7.0224698488	Double Read
					VISIT 7	05APR2016	14:37	20.322677085	Double Read
					VISIT 8	05APR2017	13:36	13.672974350	Double Read
					VISIT 11	16MAR2020	14:40	17.485850178	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	19JAN2015	13:03	11.8444980465	Double Read
					VISIT 3A	14APR2015	15:23	9.25768642772	Double Read
					VISIT 4	01JUN2015	14:15	3.30187192118	Double Read
					VISIT 6	06OCT2015	14:15	9.05950738916	Double Read
					VISIT 7	05APR2016	14:37	11.5100934262	Double Read
					VISIT 8	05APR2017	13:36	9.1964396127	Double Read
					VISIT 11	16MAR2020	14:40	13.3903040598	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	19JAN2015	13:03	6303.5	Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	19JAN2015	13:03	11427.0	Double Read
					VISIT 3A	14APR2015	15:23	9928.0	Double Read
					VISIT 4	01JUN2015	14:15	11142.5	Double Read
					VISIT 6	06OCT2015	14:15	9844.0	Double Read
					VISIT 7	05APR2016	14:37	11628.0	Double Read
					VISIT 8	05APR2017	13:36	11928.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0607 Age=59 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 11	16MAR2020	14:40	10294.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	19JAN2015	13:03	13348.0	Double Read
					VISIT 3A	14APR2015	15:23	12444.0	Double Read
					VISIT 4	01JUN2015	14:15	12622.5	Double Read
					VISIT 6	06OCT2015	14:15	11950.5	Double Read
					VISIT 7	05APR2016	14:37	13879.5	Double Read
					VISIT 8	05APR2017	13:36	12887.5	Double Read
					VISIT 11	16MAR2020	14:40	11831.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	19JAN2015	13:03		Double Read
					VISIT 3A	14APR2015	15:23		Double Read
					VISIT 4	01JUN2015	14:15		Double Read
					VISIT 6	06OCT2015	14:15		Double Read
					VISIT 7	05APR2016	14:37		Double Read
					VISIT 8	05APR2017	13:36		Double Read
					VISIT 11	16MAR2020	14:40		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0608 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	28JAN2015	13:38	4	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28JAN2015	13:38	3	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	28JAN2015	13:38	N	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28JAN2015	13:38	N	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	28JAN2015	13:38	Y	Double Read
					UNSCHEDULED	26JAN2015	13:24	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28JAN2015	13:38	N	Double Read
					UNSCHEDULED	26JAN2015	13:24	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	28JAN2015	13:38	N	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Fracture	5_S		General		Baseline	28JAN2015	13:38	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0608 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Fracture	5_S		General		UNSCHEDULED	26JAN2015	13:24		Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	28JAN2015	13:38	14.18	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	28JAN2015	13:38	16.02	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	28JAN2015	13:38	8.42249	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	28JAN2015	13:38	13.87825	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	28JAN2015	13:38	N	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0608 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28JAN2015	13:38	N	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	28JAN2015	13:38	N	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28JAN2015	13:38	N	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Normal lordotic LS	5_S		General		Baseline	28JAN2015	13:38	Y	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	28JAN2015	13:38	0	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28JAN2015	13:38	0	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	28JAN2015	13:38	N	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0608 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28JAN2015	13:38	N	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Relevant scoliosis	5_S		General		Baseline	28JAN2015	13:38	N	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	28JAN2015	13:38	N	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	28JAN2015	13:38	N	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	28JAN2015	13:38	59.10768	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0608 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	28JAN2015	13:38	74.29472	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0608 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	28JAN2015	13:38	lower	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0608 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	28JAN2015	13:38	6.36241888908	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	28JAN2015	13:38	7.00725666723	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	28JAN2015	13:38		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0608 Age=45 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	UNSCHEDULED	26JAN2015	13:24		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	28JAN2015	13:38	13376.0	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	28JAN2015	13:38	20929.5	Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	28JAN2015	13:38		Double Read
					UNSCHEDULED	26JAN2015	13:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0609 Age=22 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	15APR2015	13:16		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	15APR2015	13:16	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15APR2015	13:16	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	15APR2015	13:16		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	15APR2015	13:16	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15APR2015	13:16	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	15APR2015	13:16		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	15APR2015	13:16	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15APR2015	13:16	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	15APR2015	13:16	N	Double Read
Fracture	5_S		General		Baseline	15APR2015	13:16	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15APR2015	13:16		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15APR2015	13:16	10.445	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15APR2015	13:16	10.425	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0609 Age=22 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15APR2015	13:16		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15APR2015	13:16	6.958235	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15APR2015	13:16	8.72384	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	15APR2015	13:16		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	15APR2015	13:16	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15APR2015	13:16	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	15APR2015	13:16		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	15APR2015	13:16	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15APR2015	13:16	N	Double Read
Normal lordotic LS	5_S		General		Baseline	15APR2015	13:16	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	15APR2015	13:16		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	15APR2015	13:16	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0609 Age=22 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15APR2015	13:16	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	15APR2015	13:16		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	15APR2015	13:16	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15APR2015	13:16	N	Double Read
Relevant scoliosis	5_S		General		Baseline	15APR2015	13:16	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	15APR2015	13:16		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	15APR2015	13:16	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15APR2015	13:16	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	15APR2015	13:16		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15APR2015	13:16		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	15APR2015	13:16		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	15APR2015	13:16		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15APR2015	13:16	68.87472	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	15APR2015	13:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0609 Age=22 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15APR2015	13:16		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15APR2015	13:16	83.72704	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	15APR2015	13:16		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	15APR2015	13:16		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	15APR2015	13:16		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	15APR2015	13:16		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	15APR2015	13:16		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	15APR2015	13:16		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	15APR2015	13:16		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	15APR2015	13:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0609 Age=22 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	15APR2015	13:16	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	15APR2015	13:16		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	15APR2015	13:16		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	15APR2015	13:16		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	15APR2015	13:16		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	15APR2015	13:16		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15APR2015	13:16		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	15APR2015	13:16		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	15APR2015	13:16		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15APR2015	13:16	6.70403940887	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	15APR2015	13:16		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15APR2015	13:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0609 Age=22 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15APR2015	13:16	2.85536945813	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	15APR2015	13:16		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	15APR2015	13:16		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15APR2015	13:16		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	15APR2015	13:16		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	15APR2015	13:16		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15APR2015	13:16	7411.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	15APR2015	13:16		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15APR2015	13:16		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15APR2015	13:16	8317.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	15APR2015	13:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0610 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	24JUN2015	9:07	2	Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S	4_5	Central Disc		Baseline	24JUN2015	9:07	3	Double Read
					VISIT 3A	07SEP2015	13:24	3	Double Read
					VISIT 4	26OCT2015	14:52	3	Double Read
					VISIT 6	16MAR2016	11:31	3	Double Read
					VISIT 7	30AUG2016	14:34	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	24JUN2015	9:07	2	Double Read
					VISIT 3A	07SEP2015	13:24	2	Double Read
					VISIT 4	26OCT2015	14:52	2	Double Read
					VISIT 6	16MAR2016	11:31	2	Double Read
					VISIT 7	30AUG2016	14:34	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S	4_5	Central Disc		Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24	N	Double Read
					VISIT 4	26OCT2015	14:52	N	Double Read
					VISIT 6	16MAR2016	11:31	N	Double Read
					VISIT 7	30AUG2016	14:34	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0610 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 4	26OCT2015	14:52	N	Double Read
					VISIT 6	16MAR2016	11:31	N	Double Read
					VISIT 7	30AUG2016	14:34	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
Dorsal disc extrusion (Central Disc)	5_S	4_5	Central Disc		Baseline	24JUN2015	9:07	Y	Double Read
					VISIT 3A	07SEP2015	13:24	Y	Double Read
					VISIT 4	26OCT2015	14:52	Y	Double Read
					VISIT 6	16MAR2016	11:31	Y	Double Read
					VISIT 7	30AUG2016	14:34	Y	Double Read
Dorsal disc extrusion (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24	Y	Double Read
					VISIT 4	26OCT2015	14:52	N	Double Read
					VISIT 6	16MAR2016	11:31	N	Double Read
Extradiscal fluid collection	5_S	4_5	General		VISIT 7	30AUG2016	14:34	Y	Double Read
					Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24	N	Double Read
					VISIT 4	26OCT2015	14:52	N	Double Read
					VISIT 6	16MAR2016	11:31	N	Double Read
Fracture	5_S	4_5	General		VISIT 7	30AUG2016	14:34	N	Double Read
					Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24	N	Double Read
					VISIT 4	26OCT2015	14:52	N	Double Read
					VISIT 6	16MAR2016	11:31	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	24JUN2015	9:07	6.695	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0610 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	24JUN2015	9:07	13.94	Double Read
					VISIT 3A	07SEP2015	13:24	14.43	Double Read
					VISIT 4	26OCT2015	14:52	13.945	Double Read
					VISIT 6	16MAR2016	11:31	12.69	Double Read
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	VISIT 7	30AUG2016	14:34	13.285	Double Read
					Baseline	24JUN2015	9:07	10.685	Double Read
					VISIT 3A	07SEP2015	13:24	12.005	Double Read
					VISIT 4	26OCT2015	14:52	11.515	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	VISIT 6	16MAR2016	11:31	12.915	Double Read
					VISIT 7	30AUG2016	14:34	10.885	Double Read
					Baseline	24JUN2015	9:07	5.66318	Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
					Baseline	24JUN2015	9:07	8.32122	Double Read
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	VISIT 3A	07SEP2015	13:24	7.56767	Double Read
					VISIT 4	26OCT2015	14:52	8.332815	Double Read
					VISIT 6	16MAR2016	11:31	7.224435	Double Read
					VISIT 7	30AUG2016	14:34	7.530035	Double Read
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	24JUN2015	9:07	9.135665	Double Read
					VISIT 3A	07SEP2015	13:24	9.1487	Double Read
					VISIT 4	26OCT2015	14:52	9.07371	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0610 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	VISIT 6	16MAR2016	11:31	9.01458	Double Read
					VISIT 7	30AUG2016	14:34	8.626045	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S	4_5	Central Disc		Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24	N	Double Read
					VISIT 4	26OCT2015	14:52	N	Double Read
					VISIT 6	16MAR2016	11:31	N	Double Read
					VISIT 7	30AUG2016	14:34	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24	N	Double Read
					VISIT 4	26OCT2015	14:52	N	Double Read
					VISIT 6	16MAR2016	11:31	N	Double Read
					VISIT 7	30AUG2016	14:34	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S	4_5	Central Disc		Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0610 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S	4_5	Central Disc		VISIT 4	26OCT2015	14:52	N	Double Read
					VISIT 6	16MAR2016	11:31	N	Double Read
					VISIT 7	30AUG2016	14:34	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24	N	Double Read
					VISIT 4	26OCT2015	14:52	N	Double Read
					VISIT 6	16MAR2016	11:31	N	Double Read
					VISIT 7	30AUG2016	14:34	N	Double Read
Normal lordotic LS	5_S	4_5	General		Baseline	24JUN2015	9:07	Y	Double Read
					VISIT 3A	07SEP2015	13:24	Y	Double Read
					VISIT 4	26OCT2015	14:52	Y	Double Read
					VISIT 6	16MAR2016	11:31	Y	Double Read
					VISIT 7	30AUG2016	14:34	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	24JUN2015	9:07	0	Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S	4_5	Central Disc		Baseline	24JUN2015	9:07	0	Double Read
					VISIT 3A	07SEP2015	13:24	0	Double Read
					VISIT 4	26OCT2015	14:52	0	Double Read
					VISIT 6	16MAR2016	11:31	1	Double Read
					VISIT 7	30AUG2016	14:34	1	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	24JUN2015	9:07	0	Double Read
					VISIT 3A	07SEP2015	13:24	0	Double Read
					VISIT 4	26OCT2015	14:52	0	Double Read
					VISIT 6	16MAR2016	11:31	0	Double Read
					VISIT 7	30AUG2016	14:34	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0610 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
Protruding osteophyte (Central Disc)	5_S	4_5	Central Disc		Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24	N	Double Read
					VISIT 4	26OCT2015	14:52	N	Double Read
					VISIT 6	16MAR2016	11:31	N	Double Read
					VISIT 7	30AUG2016	14:34	N	Double Read
Protruding osteophyte (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24	N	Double Read
					VISIT 4	26OCT2015	14:52	N	Double Read
					VISIT 6	16MAR2016	11:31	N	Double Read
					VISIT 7	30AUG2016	14:34	N	Double Read
Relevant scoliosis	5_S	4_5	General		Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24	N	Double Read
					VISIT 4	26OCT2015	14:52	N	Double Read
					VISIT 6	16MAR2016	11:31	N	Double Read
					VISIT 7	30AUG2016	14:34	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S	4_5	Central Disc		Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24	N	Double Read
					VISIT 4	26OCT2015	14:52	N	Double Read
					VISIT 6	16MAR2016	11:31	N	Double Read
					VISIT 7	30AUG2016	14:34	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0610 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	24JUN2015	9:07	N	Double Read
					VISIT 3A	07SEP2015	13:24	N	Double Read
					VISIT 4	26OCT2015	14:52	N	Double Read
					VISIT 6	16MAR2016	11:31	N	Double Read
					VISIT 7	30AUG2016	14:34	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	24JUN2015	9:07	87.54752	Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	24JUN2015	9:07	68.63184	Double Read
					VISIT 3A	07SEP2015	13:24	71.79408	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0610 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	VISIT 4	26OCT2015	14:52	67.92048	Double Read
					VISIT 6	16MAR2016	11:31	72.76208	Double Read
					VISIT 7	30AUG2016	14:34	74.8152	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2 (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2 (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	24JUN2015	9:07	93.09264	Double Read
					VISIT 3A	07SEP2015	13:24	95.55808	Double Read
					VISIT 4	26OCT2015	14:52	96.43392	Double Read
					VISIT 6	16MAR2016	11:31	91.72896	Double Read
					VISIT 7	30AUG2016	14:34	99.22352	Double Read
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0610 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S	4_5	Caudal Disc		VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S	4_5	Central Disc		Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	24JUN2015	9:07	lower	Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0610 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	24JUN2015	9:07	equal	Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	24JUN2015	9:07	lower	Double Read
					VISIT 3A	07SEP2015	13:24	lower	Double Read
					VISIT 4	26OCT2015	14:52	lower	Double Read
					VISIT 6	16MAR2016	11:31	lower	Double Read
					VISIT 7	30AUG2016	14:34	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	24JUN2015	9:07	equal	Double Read
					VISIT 3A	07SEP2015	13:24	lower	Double Read
					VISIT 4	26OCT2015	14:52	lower	Double Read
					VISIT 6	16MAR2016	11:31	lower	Double Read
					VISIT 7	30AUG2016	14:34	equal	Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0610 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S	4_5	Central Disc		Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	24JUN2015	9:07	3.12553083065	Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	24JUN2015	9:07		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0610 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	24JUN2015	9:07	10.224487854	Double Read
					VISIT 3A	07SEP2015	13:24	11.414982164	Double Read
					VISIT 4	26OCT2015	14:52	4.1657618481	Double Read
					VISIT 6	16MAR2016	11:31	17.740037370	Double Read
					VISIT 7	30AUG2016	14:34	20.519925259	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	24JUN2015	9:07	2.0707457108	Double Read
					VISIT 3A	07SEP2015	13:24	4.7562425683	Double Read
					VISIT 4	26OCT2015	14:52	2.3101749617	Double Read
					VISIT 6	16MAR2016	11:31	19.896857482	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0610 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	VISIT 7	30AUG2016	14:34	15.9196874469	Double Read
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	24JUN2015	9:07	4190.5	Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0610 Age=31 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	24JUN2015	9:07	10757.5	Double Read
					VISIT 3A	07SEP2015	13:24	10461.5	Double Read
					VISIT 4	26OCT2015	14:52	10200.0	Double Read
					VISIT 6	16MAR2016	11:31	10318.5	Double Read
					VISIT 7	30AUG2016	14:34	10555.5	Double Read
Volume (mm ³) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
Volume (mm ³) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read
Volume (mm ³) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	24JUN2015	9:07	9877.0	Double Read
					VISIT 3A	07SEP2015	13:24	10650.0	Double Read
					VISIT 4	26OCT2015	14:52	9714.5	Double Read
					VISIT 6	16MAR2016	11:31	10791.5	Double Read
					VISIT 7	30AUG2016	14:34	10579.5	Double Read
Volume (mm ³) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	24JUN2015	9:07		Double Read
					VISIT 3A	07SEP2015	13:24		Double Read
					VISIT 4	26OCT2015	14:52		Double Read
					VISIT 6	16MAR2016	11:31		Double Read
					VISIT 7	30AUG2016	14:34		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0611 Age=39 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUL2015	12:13		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	14JUL2015	12:13	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	12:13	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUL2015	12:13		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	14JUL2015	12:13	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	12:13	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUL2015	12:13		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	14JUL2015	12:13	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	12:13	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	14JUL2015	12:13	N	Double Read
Fracture	5_S		General		Baseline	14JUL2015	12:13	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JUL2015	12:13		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JUL2015	12:13	17.51	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	12:13	16.43	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0611 Age=39 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JUL2015	12:13		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JUL2015	12:13	12.91285	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	12:13	13.2969	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUL2015	12:13		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	14JUL2015	12:13	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	12:13	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUL2015	12:13		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	14JUL2015	12:13	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	12:13	N	Double Read
Normal lordotic LS	5_S		General		Baseline	14JUL2015	12:13	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUL2015	12:13		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	14JUL2015	12:13	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0611 Age=39 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	12:13	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUL2015	12:13		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	14JUL2015	12:13	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	12:13	N	Double Read
Relevant scoliosis	5_S		General		Baseline	14JUL2015	12:13	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	14JUL2015	12:13		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	14JUL2015	12:13	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	12:13	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	14JUL2015	12:13		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JUL2015	12:13		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	14JUL2015	12:13		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	14JUL2015	12:13		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JUL2015	12:13	77.67904	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	14JUL2015	12:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0611 Age=39 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JUL2015	12:13		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	12:13	98.40576	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	14JUL2015	12:13		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JUL2015	12:13		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	14JUL2015	12:13		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	12:13		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JUL2015	12:13		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	14JUL2015	12:13		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	12:13		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JUL2015	12:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0611 Age=39 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	14JUL2015	12:13	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	12:13		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JUL2015	12:13		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	14JUL2015	12:13		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JUL2015	12:13		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	14JUL2015	12:13		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JUL2015	12:13		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	14JUL2015	12:13		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	14JUL2015	12:13		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JUL2015	12:13	6.11208425344	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	14JUL2015	12:13		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JUL2015	12:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0611 Age=39 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	12:13	2.72917954815	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	14JUL2015	12:13		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	14JUL2015	12:13		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JUL2015	12:13		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	14JUL2015	12:13		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	14JUL2015	12:13		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JUL2015	12:13	18458.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	14JUL2015	12:13		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JUL2015	12:13		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	12:13	19186.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	14JUL2015	12:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	14JUL2015	11:27	3	Double Read
					VISIT 3A	19OCT2015	11:20	3	Double Read
					VISIT 4	25NOV2015	13:20	3	Double Read
					VISIT 6	11APR2016	14:02	3	Double Read
					VISIT 7	26OCT2016	13:41	4	Double Read
					VISIT 8	19OCT2017	14:08	3	Double Read
					VISIT 11	14OCT2020	13:56	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	14JUL2015	11:27	3	Double Read
					VISIT 3A	19OCT2015	11:20	3	Double Read
					VISIT 4	25NOV2015	13:20	4	Double Read
					VISIT 6	11APR2016	14:02	3	Double Read
					VISIT 7	26OCT2016	13:41	3	Double Read
					VISIT 8	19OCT2017	14:08	3	Double Read
					VISIT 11	14OCT2020	13:56	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	11:27	3	Double Read
					VISIT 3A	19OCT2015	11:20	3	Double Read
					VISIT 4	25NOV2015	13:20	4	Double Read
					VISIT 6	11APR2016	14:02	4	Double Read
					VISIT 7	26OCT2016	13:41	4	Double Read
					VISIT 8	19OCT2017	14:08	3	Double Read
					VISIT 11	14OCT2020	13:56	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read
					VISIT 7	26OCT2016	13:41	N	Double Read
					VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	14JUL2015	11:27	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read
					VISIT 7	26OCT2016	13:41	N	Double Read
					VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read
					VISIT 7	26OCT2016	13:41	N	Double Read
					VISIT 8	19OCT2017	14:08	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 11	14OCT2020	13:56	N	Double Read
					Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read
					VISIT 7	26OCT2016	13:41	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read
					Baseline	14JUL2015	11:27	Y	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	Y	Double Read
					VISIT 6	11APR2016	14:02	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	26OCT2016	13:41	Y	Double Read
					VISIT 8	19OCT2017	14:08	Y	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read
					Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	26OCT2016	13:41	N	Double Read
					VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read
					VISIT 7	26OCT2016	13:41	N	Double Read
					VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read
Fracture	4_5		General		Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read
					VISIT 7	26OCT2016	13:41	N	Double Read
					VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	14JUL2015	11:27	14.515	Double Read
					VISIT 3A	19OCT2015	11:20	14.82	Double Read
					VISIT 4	25NOV2015	13:20	15.085	Double Read
					VISIT 6	11APR2016	14:02	14.725	Double Read
					VISIT 7	26OCT2016	13:41	15.825	Double Read
					VISIT 8	19OCT2017	14:08	13.65	Double Read
					VISIT 11	14OCT2020	13:56	15.855	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	14JUL2015	11:27	14.165	Double Read
					VISIT 3A	19OCT2015	11:20	14.33	Double Read
					VISIT 4	25NOV2015	13:20	15.84	Double Read
					VISIT 6	11APR2016	14:02	15.01	Double Read
					VISIT 7	26OCT2016	13:41	14.855	Double Read
					VISIT 8	19OCT2017	14:08	13.075	Double Read
					VISIT 11	14OCT2020	13:56	12.97	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	11:27	13.29	Double Read
					VISIT 3A	19OCT2015	11:20	13.21	Double Read
					VISIT 4	25NOV2015	13:20	13.805	Double Read
					VISIT 6	11APR2016	14:02	13.695	Double Read
					VISIT 7	26OCT2016	13:41	12.84	Double Read
					VISIT 8	19OCT2017	14:08	11.78	Double Read
					VISIT 11	14OCT2020	13:56	11.585	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	14JUL2015	11:27	9.36806	Double Read
					VISIT 3A	19OCT2015	11:20	9.430955	Double Read
					VISIT 4	25NOV2015	13:20	8.63038	Double Read
					VISIT 6	11APR2016	14:02	9.075245	Double Read
					VISIT 7	26OCT2016	13:41	8.623375	Double Read
					VISIT 8	19OCT2017	14:08	9.070045	Double Read
					VISIT 11	14OCT2020	13:56	9.718035	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	14JUL2015	11:27	10.4974	Double Read
					VISIT 3A	19OCT2015	11:20	9.822905	Double Read
					VISIT 4	25NOV2015	13:20	8.899525	Double Read
					VISIT 6	11APR2016	14:02	9.6075	Double Read
					VISIT 7	26OCT2016	13:41	9.109845	Double Read
					VISIT 8	19OCT2017	14:08	9.340755	Double Read
					VISIT 11	14OCT2020	13:56	9.485255	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	11:27	11.0989	Double Read
					VISIT 3A	19OCT2015	11:20	10.65535	Double Read
					VISIT 4	25NOV2015	13:20	10.214525	Double Read
					VISIT 6	11APR2016	14:02	10.352895	Double Read
					VISIT 7	26OCT2016	13:41	10.01101	Double Read
					VISIT 8	19OCT2017	14:08	9.664075	Double Read
					VISIT 11	14OCT2020	13:56	9.91633	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read
					VISIT 7	26OCT2016	13:41	N	Double Read
					VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	Y	Double Read
					VISIT 7	26OCT2016	13:41	N	Double Read
					VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read
					VISIT 7	26OCT2016	13:41	N	Double Read
					VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read
					VISIT 7	26OCT2016	13:41	N	Double Read
					VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read
					VISIT 7	26OCT2016	13:41	N	Double Read
					VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read
					VISIT 7	26OCT2016	13:41	N	Double Read
					VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read
Normal lordotic LS	4_5		General		Baseline	14JUL2015	11:27	Y	Double Read
					VISIT 3A	19OCT2015	11:20	Y	Double Read
					VISIT 4	25NOV2015	13:20	Y	Double Read
					VISIT 6	11APR2016	14:02	Y	Double Read
					VISIT 7	26OCT2016	13:41	Y	Double Read
					VISIT 8	19OCT2017	14:08	Y	Double Read
					VISIT 11	14OCT2020	13:56	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	14JUL2015	11:27	0	Double Read
					VISIT 3A	19OCT2015	11:20	0	Double Read
					VISIT 4	25NOV2015	13:20	0	Double Read
					VISIT 6	11APR2016	14:02	0	Double Read
					VISIT 7	26OCT2016	13:41	0	Double Read
					VISIT 8	19OCT2017	14:08	0	Double Read
					VISIT 11	14OCT2020	13:56	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	14JUL2015	11:27	0	Double Read
					VISIT 3A	19OCT2015	11:20	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 4	25NOV2015	13:20	0	Double Read
					VISIT 6	11APR2016	14:02	0	Double Read
					VISIT 7	26OCT2016	13:41	0	Double Read
					VISIT 8	19OCT2017	14:08	0	Double Read
					VISIT 11	14OCT2020	13:56	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	11:27	0	Double Read
					VISIT 3A	19OCT2015	11:20	0	Double Read
					VISIT 4	25NOV2015	13:20	0	Double Read
					VISIT 6	11APR2016	14:02	0	Double Read
					VISIT 7	26OCT2016	13:41	0	Double Read
					VISIT 8	19OCT2017	14:08	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 11	14OCT2020	13:56	0	Double Read
					Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read
					VISIT 7	26OCT2016	13:41	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read
					Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	26OCT2016	13:41	N	Double Read
					VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read
					Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read
					VISIT 7	26OCT2016	13:41	N	Double Read
					VISIT 8	19OCT2017	14:08	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read
Relevant scoliosis	4_5		General		Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read
					VISIT 7	26OCT2016	13:41	N	Double Read
					VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read
					VISIT 7	26OCT2016	13:41	N	Double Read
					VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read
					VISIT 7	26OCT2016	13:41	N	Double Read
					VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	11:27	N	Double Read
					VISIT 3A	19OCT2015	11:20	N	Double Read
					VISIT 4	25NOV2015	13:20	N	Double Read
					VISIT 6	11APR2016	14:02	N	Double Read
					VISIT 7	26OCT2016	13:41	N	Double Read
					VISIT 8	19OCT2017	14:08	N	Double Read
					VISIT 11	14OCT2020	13:56	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20	61.13088	Double Read
					VISIT 4	25NOV2015	13:20	68.73472	Double Read
					VISIT 6	11APR2016	14:02	74.64432	Double Read
					VISIT 7	26OCT2016	13:41	82.35456	Double Read
					VISIT 8	19OCT2017	14:08	71.61616	Double Read
					VISIT 11	14OCT2020	13:56	64.30992	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	14JUL2015	11:27		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	19OCT2015	11:20	71.00368	Double Read
					VISIT 4	25NOV2015	13:20	66.14144	Double Read
					VISIT 6	11APR2016	14:02	77.55472	Double Read
					VISIT 7	26OCT2016	13:41	74.18208	Double Read
					VISIT 8	19OCT2017	14:08	72.79616	Double Read
					VISIT 11	14OCT2020	13:56	67.30224	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20	62.1848	Double Read
					VISIT 4	25NOV2015	13:20	62.23888	Double Read
					VISIT 6	11APR2016	14:02	74.00272	Double Read
					VISIT 7	26OCT2016	13:41	70.6064	Double Read
					VISIT 8	19OCT2017	14:08	65.40208	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	14OCT2020	13:56	68.24304	Double Read
					VISIT 3A	19OCT2015	11:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	14JUL2015	11:27	equal	Double Read
					VISIT 3A	19OCT2015	11:20	higher	Double Read
					VISIT 4	25NOV2015	13:20	higher	Double Read
					VISIT 6	11APR2016	14:02	equal	Double Read
					VISIT 7	26OCT2016	13:41	higher	Double Read
					VISIT 8	19OCT2017	14:08	equal	Double Read
					VISIT 11	14OCT2020	13:56	equal	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		VISIT 11	14OCT2020	13:56		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	14JUL2015	11:27	equal	Double Read
					VISIT 3A	19OCT2015	11:20	higher	Double Read
					VISIT 4	25NOV2015	13:20	higher	Double Read
					VISIT 6	11APR2016	14:02	higher	Double Read
					VISIT 7	26OCT2016	13:41	higher	Double Read
					VISIT 8	19OCT2017	14:08	equal	Double Read
					VISIT 11	14OCT2020	13:56	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20	15.7033463563	Double Read
					VISIT 4	25NOV2015	13:20	15.4043825378	Double Read
					VISIT 6	11APR2016	14:02	9.72786818414	Double Read
					VISIT 7	26OCT2016	13:41	9.11559028368	Double Read
					VISIT 8	19OCT2017	14:08	14.0163750637	Double Read
					VISIT 11	14OCT2020	13:56	10.5660608119	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20	3.39731612026	Double Read
					VISIT 4	25NOV2015	13:20	4.64735179208	Double Read
					VISIT 6	11APR2016	14:02	16.3211143197	Double Read
					VISIT 7	26OCT2016	13:41	12.5002344148	Double Read
					VISIT 8	19OCT2017	14:08	16.8532699168	Double Read
					VISIT 11	14OCT2020	13:56	13.2122982844	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20	10.3467096994	Double Read
					VISIT 4	25NOV2015	13:20	10.2027314421	Double Read
					VISIT 6	11APR2016	14:02	20.2857142857	Double Read
					VISIT 7	26OCT2016	13:41	13.4632444369	Double Read
					VISIT 8	19OCT2017	14:08	11.6220214031	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	14OCT2020	13:56	15.489736708	Double Read
					Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	14JUL2015	11:27	14467.0	Double Read
					VISIT 3A	19OCT2015	11:20	13547.5	Double Read
					VISIT 4	25NOV2015	13:20	13805.0	Double Read
					VISIT 6	11APR2016	14:02	14365.0	Double Read
					VISIT 7	26OCT2016	13:41	14287.0	Double Read
					VISIT 8	19OCT2017	14:08	12652.5	Double Read
					VISIT 11	14OCT2020	13:56	14216.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	14JUL2015	11:27	18672.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	19OCT2015	11:20	16823.0	Double Read
					VISIT 4	25NOV2015	13:20	17838.0	Double Read
					VISIT 6	11APR2016	14:02	17020.0	Double Read
					VISIT 7	26OCT2016	13:41	17304.5	Double Read
					VISIT 8	19OCT2017	14:08	15888.5	Double Read
					VISIT 11	14OCT2020	13:56	15867.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JUL2015	11:27		Double Read
					VISIT 3A	19OCT2015	11:20		Double Read
					VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	11:27	20083.5	Double Read
					VISIT 3A	19OCT2015	11:20	17914.5	Double Read
					VISIT 4	25NOV2015	13:20	18338.0	Double Read
					VISIT 6	11APR2016	14:02	18750.5	Double Read
					VISIT 7	26OCT2016	13:41	18062.0	Double Read
					VISIT 8	19OCT2017	14:08	16654.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	14OCT2020	13:56	16670.5	Double Read
					VISIT 3A	19OCT2015	11:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0612 Age=58 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	25NOV2015	13:20		Double Read
					VISIT 6	11APR2016	14:02		Double Read
					VISIT 7	26OCT2016	13:41		Double Read
					VISIT 8	19OCT2017	14:08		Double Read
					VISIT 11	14OCT2020	13:56		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0613 Age=51 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirschmann) (Caudal Disc)	3_4		Caudal Disc		Baseline	17JUL2015	13:22	3	Double Read
					VISIT 4	04SEP2015	11:20	3	Double Read
					VISIT 6	15JAN2016	10:17	4	Double Read
					VISIT 7	15JUL2016	10:01	3	Double Read
					VISIT 8	09AUG2017	12:29	3	Double Read
					VISIT 11	11AUG2020	12:47	2	Double Read
Disc degeneration grading (Pfirschmann) (Central Disc)	3_4		Central Disc		Baseline	17JUL2015	13:22	3	Double Read
					VISIT 4	04SEP2015	11:20	3	Double Read
					VISIT 6	15JAN2016	10:17	3	Double Read
					VISIT 7	15JUL2016	10:01	3	Double Read
					VISIT 8	09AUG2017	12:29	3	Double Read
					VISIT 11	11AUG2020	12:47	3	Double Read
Disc degeneration grading (Pfirschmann) (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	17JUL2015	13:22	2	Double Read
					VISIT 4	04SEP2015	11:20	2	Double Read
					VISIT 6	15JAN2016	10:17	2	Double Read
					VISIT 7	15JUL2016	10:01	2	Double Read
					VISIT 8	09AUG2017	12:29	2	Double Read
					VISIT 11	11AUG2020	12:47	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	3_4		Caudal Disc		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read
					VISIT 11	11AUG2020	12:47	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	3_4		Central Disc		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0613 Age=51 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	3_4		Central Disc		VISIT 11	11AUG2020	12:47	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read
					VISIT 11	11AUG2020	12:47	N	Double Read
Dorsal disc extrusion (Caudal Disc)	3_4		Caudal Disc		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read
					VISIT 11	11AUG2020	12:47	N	Double Read
Dorsal disc extrusion (Central Disc)	3_4		Central Disc		Baseline	17JUL2015	13:22	Y	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read
					VISIT 11	11AUG2020	12:47	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read
					VISIT 11	11AUG2020	12:47	N	Double Read
Extradiscal fluid collection	3_4		General		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0613 Age=51 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	3_4		General		VISIT 11	11AUG2020	12:47	N	Double Read
Fracture	3_4		General		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read
					VISIT 11	11AUG2020	12:47	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	17JUL2015	13:22	14.04	Double Read
					VISIT 4	04SEP2015	11:20	16.095	Double Read
					VISIT 6	15JAN2016	10:17	16.16	Double Read
					VISIT 7	15JUL2016	10:01	14.65	Double Read
					VISIT 8	09AUG2017	12:29	14.125	Double Read
					VISIT 11	11AUG2020	12:47	12.425	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	17JUL2015	13:22	11.735	Double Read
					VISIT 4	04SEP2015	11:20	14.74	Double Read
					VISIT 6	15JAN2016	10:17	13.605	Double Read
					VISIT 7	15JUL2016	10:01	13.85	Double Read
					VISIT 8	09AUG2017	12:29	13.405	Double Read
					VISIT 11	11AUG2020	12:47	13.755	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	17JUL2015	13:22	13.86	Double Read
					VISIT 4	04SEP2015	11:20	15.71	Double Read
					VISIT 6	15JAN2016	10:17	15.195	Double Read
					VISIT 7	15JUL2016	10:01	15.27	Double Read
					VISIT 8	09AUG2017	12:29	15.705	Double Read
					VISIT 11	11AUG2020	12:47	13.865	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	17JUL2015	13:22	9.66865	Double Read
					VISIT 4	04SEP2015	11:20	10.7435	Double Read
					VISIT 6	15JAN2016	10:17	10.32944	Double Read
					VISIT 7	15JUL2016	10:01	9.55347	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0613 Age=51 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	VISIT 8	09AUG2017	12:29	9.945135	Double Read
					VISIT 11	11AUG2020	12:47	9.124915	Double Read
Height manual (mm) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	17JUL2015	13:22	10.187695	Double Read
					VISIT 4	04SEP2015	11:20	11.41625	Double Read
					VISIT 6	15JAN2016	10:17	11.09705	Double Read
					VISIT 7	15JUL2016	10:01	11.28965	Double Read
					VISIT 8	09AUG2017	12:29	11.7828	Double Read
					VISIT 11	11AUG2020	12:47	11.26015	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	17JUL2015	13:22	13.0014	Double Read
					VISIT 4	04SEP2015	11:20	12.00145	Double Read
					VISIT 6	15JAN2016	10:17	13.82675	Double Read
					VISIT 7	15JUL2016	10:01	13.34305	Double Read
					VISIT 8	09AUG2017	12:29	14.2343	Double Read
					VISIT 11	11AUG2020	12:47	13.4544	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	3_4		Caudal Disc		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read
					VISIT 11	11AUG2020	12:47	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	3_4		Central Disc		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read
					VISIT 11	11AUG2020	12:47	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0613 Age=51 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read
					VISIT 11	11AUG2020	12:47	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	3_4		Caudal Disc		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read
					VISIT 11	11AUG2020	12:47	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	3_4		Central Disc		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read
					VISIT 11	11AUG2020	12:47	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read
					VISIT 11	11AUG2020	12:47	N	Double Read
Normal lordotic LS	3_4		General		Baseline	17JUL2015	13:22	Y	Double Read
					VISIT 4	04SEP2015	11:20	Y	Double Read
					VISIT 6	15JAN2016	10:17	Y	Double Read
					VISIT 7	15JUL2016	10:01	Y	Double Read
					VISIT 8	09AUG2017	12:29	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0613 Age=51 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	3_4		General		VISIT 11	11AUG2020	12:47	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	3_4		Caudal Disc		Baseline	17JUL2015	13:22	0	Double Read
					VISIT 4	04SEP2015	11:20	0	Double Read
					VISIT 6	15JAN2016	10:17	0	Double Read
					VISIT 7	15JUL2016	10:01	0	Double Read
					VISIT 8	09AUG2017	12:29	0	Double Read
					VISIT 11	11AUG2020	12:47	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	3_4		Central Disc		Baseline	17JUL2015	13:22	0	Double Read
					VISIT 4	04SEP2015	11:20	0	Double Read
					VISIT 6	15JAN2016	10:17	0	Double Read
					VISIT 7	15JUL2016	10:01	0	Double Read
					VISIT 8	09AUG2017	12:29	0	Double Read
					VISIT 11	11AUG2020	12:47	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	17JUL2015	13:22	0	Double Read
					VISIT 4	04SEP2015	11:20	0	Double Read
					VISIT 6	15JAN2016	10:17	0	Double Read
					VISIT 7	15JUL2016	10:01	0	Double Read
					VISIT 8	09AUG2017	12:29	0	Double Read
					VISIT 11	11AUG2020	12:47	0	Double Read
Protruding osteophyte (Caudal Disc)	3_4		Caudal Disc		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read
					VISIT 11	11AUG2020	12:47	N	Double Read
Protruding osteophyte (Central Disc)	3_4		Central Disc		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0613 Age=51 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	3_4		Central Disc		VISIT 11	11AUG2020	12:47	Y	Double Read
Protruding osteophyte (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read
					VISIT 11	11AUG2020	12:47	N	Double Read
Relevant scoliosis	3_4		General		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read
					VISIT 11	11AUG2020	12:47	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	3_4		Caudal Disc		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read
					VISIT 11	11AUG2020	12:47	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	3_4		Central Disc		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read
					VISIT 8	09AUG2017	12:29	N	Double Read
					VISIT 11	11AUG2020	12:47	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	17JUL2015	13:22	N	Double Read
					VISIT 4	04SEP2015	11:20	N	Double Read
					VISIT 6	15JAN2016	10:17	N	Double Read
					VISIT 7	15JUL2016	10:01	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0613 Age=51 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		VISIT 8	09AUG2017	12:29	N	Double Read
					VISIT 11	11AUG2020	12:47	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	17JUL2015	13:22	57.58352	Double Read
					VISIT 4	04SEP2015	11:20	62.14624	Double Read
					VISIT 6	15JAN2016	10:17	63.35328	Double Read
					VISIT 7	15JUL2016	10:01	82.62464	Double Read
					VISIT 8	09AUG2017	12:29	71.14816	Double Read
					VISIT 11	11AUG2020	12:47	81.84256	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
T2 (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	17JUL2015	13:22	70.5608	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0613 Age=51 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	VISIT 4	04SEP2015	11:20	72.79504	Double Read
					VISIT 6	15JAN2016	10:17	69.12592	Double Read
					VISIT 7	15JUL2016	10:01	88.70896	Double Read
					VISIT 8	09AUG2017	12:29	80.00512	Double Read
					VISIT 11	11AUG2020	12:47	68.81424	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	17JUL2015	13:22	95.8336	Double Read
					VISIT 4	04SEP2015	11:20	93.55392	Double Read
					VISIT 6	15JAN2016	10:17	95.26432	Double Read
					VISIT 7	15JUL2016	10:01	108.21312	Double Read
					VISIT 8	09AUG2017	12:29	100.53216	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	11AUG2020	12:47	95.1488	Double Read
					Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0613 Age=51 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	3_4		Caudal Disc		Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	3_4		Central Disc		Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	3_4		Caudal Disc		Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0613 Age=51 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	3_4		Central Disc		Baseline	17JUL2015	13:22	higher	Double Read
					VISIT 4	04SEP2015	11:20	equal	Double Read
					VISIT 6	15JAN2016	10:17	higher	Double Read
					VISIT 7	15JUL2016	10:01	equal	Double Read
					VISIT 8	09AUG2017	12:29	equal	Double Read
					VISIT 11	11AUG2020	12:47	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	3_4		Caudal Disc		Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	3_4		Central Disc		Baseline	17JUL2015	13:22	lower	Double Read
					VISIT 4	04SEP2015	11:20	lower	Double Read
					VISIT 6	15JAN2016	10:17	lower	Double Read
					VISIT 7	15JUL2016	10:01	lower	Double Read
					VISIT 8	09AUG2017	12:29	lower	Double Read
					VISIT 11	11AUG2020	12:47	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0613 Age=51 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	3_4		Caudal Disc		Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	3_4		Central Disc		Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0613 Age=51 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	17JUL2015	13:22	9.6353592661	Double Read
					VISIT 4	04SEP2015	11:20	14.261185663	Double Read
					VISIT 6	15JAN2016	10:17	17.000713436	Double Read
					VISIT 7	15JUL2016	10:01	18.817326312	Double Read
					VISIT 8	09AUG2017	12:29	17.897740784	Double Read
					VISIT 11	11AUG2020	12:47	28.630609818	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
T2_error (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	17JUL2015	13:22	4.0999422456	Double Read
					VISIT 4	04SEP2015	11:20	9.8683947681	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0613 Age=51 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	VISIT 6	15JAN2016	10:17	7.27457108884	Double Read
					VISIT 7	15JUL2016	10:01	16.5531510107	Double Read
					VISIT 8	09AUG2017	12:29	11.6130592831	Double Read
					VISIT 11	11AUG2020	12:47	9.80292169186	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	17JUL2015	13:22	10.2032682181	Double Read
					VISIT 4	04SEP2015	11:20	9.92018345508	Double Read
					VISIT 6	15JAN2016	10:17	12.6477322915	Double Read
					VISIT 7	15JUL2016	10:01	28.9197893665	Double Read
					VISIT 8	09AUG2017	12:29	21.0331917785	Double Read
					VISIT 11	11AUG2020	12:47	23.2322745031	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0613 Age=51 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	17JUL2015	13:22	20105.5	Double Read
					VISIT 4	04SEP2015	11:20	21623.0	Double Read
					VISIT 6	15JAN2016	10:17	22002.5	Double Read
					VISIT 7	15JUL2016	10:01	22794.0	Double Read
					VISIT 8	09AUG2017	12:29	21549.5	Double Read
					VISIT 11	11AUG2020	12:47	20112.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0613 Age=51 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	VISIT 11	11AUG2020	12:47		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	17JUL2015	13:22	18981.5	Double Read
					VISIT 4	04SEP2015	11:20	20764.0	Double Read
					VISIT 6	15JAN2016	10:17	22706.0	Double Read
					VISIT 7	15JUL2016	10:01	23794.0	Double Read
					VISIT 8	09AUG2017	12:29	21992.5	Double Read
					VISIT 11	11AUG2020	12:47	22768.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read
					VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	17JUL2015	13:22	22162.5	Double Read
					VISIT 4	04SEP2015	11:20	25030.0	Double Read
					VISIT 6	15JAN2016	10:17	24925.0	Double Read
					VISIT 7	15JUL2016	10:01	25060.0	Double Read
					VISIT 8	09AUG2017	12:29	24395.0	Double Read
					VISIT 11	11AUG2020	12:47	24561.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	17JUL2015	13:22		Double Read
					VISIT 4	04SEP2015	11:20		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0613 Age=51 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	VISIT 6	15JAN2016	10:17		Double Read
					VISIT 7	15JUL2016	10:01		Double Read
					VISIT 8	09AUG2017	12:29		Double Read
					VISIT 11	11AUG2020	12:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S	4_5	Central Disc		Baseline	14AUG2015	14:04	3	Double Read
					VISIT 3A	16NOV2015	11:57	4	Double Read
					VISIT 4	04JAN2016	10:05	3	Double Read
					VISIT 6	02MAY2016	10:58	3	Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	14AUG2015	14:04	3	Double Read
					VISIT 3A	16NOV2015	11:57	3	Double Read
					VISIT 4	04JAN2016	10:05	3	Double Read
					VISIT 6	02MAY2016	10:58	3	Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S	4_5	Central Disc		Baseline	14AUG2015	14:04	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S	4_5	Central Disc		VISIT 3A	16NOV2015	11:57	N	Double Read
					VISIT 4	04JAN2016	10:05	N	Double Read
					VISIT 6	02MAY2016	10:58	N	Double Read
					VISIT 7	17NOV2016	13:53	N	Double Read
					VISIT 8	02NOV2017	13:16	N	Double Read
					VISIT 11	10DEC2020	13:52		Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	14AUG2015	14:04	N	Double Read
					VISIT 3A	16NOV2015	11:57	N	Double Read
					VISIT 4	04JAN2016	10:05	N	Double Read
					VISIT 6	02MAY2016	10:58	N	Double Read
					VISIT 7	17NOV2016	13:53	N	Double Read
					VISIT 8	02NOV2017	13:16	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S	4_5	Caudal Disc		VISIT 11	10DEC2020	13:52		Double Read
					Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
Dorsal disc extrusion (Central Disc)	5_S	4_5	Central Disc		VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
					Baseline	14AUG2015	14:04	Y	Double Read
					VISIT 3A	16NOV2015	11:57	Y	Double Read
					VISIT 4	04JAN2016	10:05	Y	Double Read
					VISIT 6	02MAY2016	10:58	Y	Double Read
Dorsal disc extrusion (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 7	17NOV2016	13:53	Y	Double Read
					VISIT 8	02NOV2017	13:16	N	Double Read
					VISIT 11	10DEC2020	13:52	N	Double Read
					Baseline	14AUG2015	14:04	N	Double Read
					VISIT 3A	16NOV2015	11:57	N	Double Read
					VISIT 4	04JAN2016	10:05	Y	Double Read
					VISIT 6	02MAY2016	10:58	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 7	17NOV2016	13:53	N	Double Read
					VISIT 8	02NOV2017	13:16	N	Double Read
					VISIT 11	10DEC2020	13:52	N	Double Read
Extradiscal fluid collection	5_S	4_5	General		Baseline	14AUG2015	14:04	N	Double Read
					VISIT 3A	16NOV2015	11:57	N	Double Read
					VISIT 4	04JAN2016	10:05	N	Double Read
					VISIT 6	02MAY2016	10:58	N	Double Read
					VISIT 7	17NOV2016	13:53	N	Double Read
					VISIT 8	02NOV2017	13:16	N	Double Read
					VISIT 11	10DEC2020	13:52	N	Double Read
Fracture	5_S	4_5	General		Baseline	14AUG2015	14:04	N	Double Read
					VISIT 3A	16NOV2015	11:57	N	Double Read
					VISIT 4	04JAN2016	10:05	N	Double Read
					VISIT 6	02MAY2016	10:58	N	Double Read
					VISIT 7	17NOV2016	13:53	N	Double Read
					VISIT 8	02NOV2017	13:16	N	Double Read
					VISIT 11	10DEC2020	13:52	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	14AUG2015	14:04	14.68	Double Read
					VISIT 3A	16NOV2015	11:57	17.04	Double Read
					VISIT 4	04JAN2016	10:05	14.46	Double Read
					VISIT 6	02MAY2016	10:58	14.38	Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	14AUG2015	14:04	14.385	Double Read
					VISIT 3A	16NOV2015	11:57	15.765	Double Read
					VISIT 4	04JAN2016	10:05	15.305	Double Read
					VISIT 6	02MAY2016	10:58	14.125	Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	14AUG2015	14:04	9.31689	Double Read
					VISIT 3A	16NOV2015	11:57	8.87737	Double Read
					VISIT 4	04JAN2016	10:05	9.067815	Double Read
					VISIT 6	02MAY2016	10:58	7.472985	Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	14AUG2015	14:04	11.9035	Double Read
					VISIT 3A	16NOV2015	11:57	11.20185	Double Read
					VISIT 4	04JAN2016	10:05	12.12235	Double Read
					VISIT 6	02MAY2016	10:58	11.23715	Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S	4_5	Central Disc		Baseline	14AUG2015	14:04	N	Double Read
					VISIT 3A	16NOV2015	11:57	N	Double Read
					VISIT 4	04JAN2016	10:05	N	Double Read
					VISIT 6	02MAY2016	10:58	N	Double Read
					VISIT 7	17NOV2016	13:53	N	Double Read
					VISIT 8	02NOV2017	13:16	N	Double Read
					VISIT 11	10DEC2020	13:52	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	14AUG2015	14:04	N	Double Read
					VISIT 3A	16NOV2015	11:57	N	Double Read
					VISIT 4	04JAN2016	10:05	N	Double Read
					VISIT 6	02MAY2016	10:58	N	Double Read
					VISIT 7	17NOV2016	13:53	N	Double Read
					VISIT 8	02NOV2017	13:16	N	Double Read
					VISIT 11	10DEC2020	13:52	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S	4_5	Central Disc		Baseline	14AUG2015	14:04	N	Double Read
					VISIT 3A	16NOV2015	11:57	N	Double Read
					VISIT 4	04JAN2016	10:05	N	Double Read
					VISIT 6	02MAY2016	10:58	N	Double Read
					VISIT 7	17NOV2016	13:53	N	Double Read
					VISIT 8	02NOV2017	13:16	N	Double Read
					VISIT 11	10DEC2020	13:52	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	14AUG2015	14:04	N	Double Read
					VISIT 3A	16NOV2015	11:57	N	Double Read
					VISIT 4	04JAN2016	10:05	N	Double Read
					VISIT 6	02MAY2016	10:58	N	Double Read
					VISIT 7	17NOV2016	13:53	N	Double Read
					VISIT 8	02NOV2017	13:16	N	Double Read
					VISIT 11	10DEC2020	13:52	N	Double Read
Normal lordotic LS	5_S	4_5	General		Baseline	14AUG2015	14:04	Y	Double Read
					VISIT 3A	16NOV2015	11:57	Y	Double Read
					VISIT 4	04JAN2016	10:05	Y	Double Read
					VISIT 6	02MAY2016	10:58	Y	Double Read
					VISIT 7	17NOV2016	13:53	Y	Double Read
					VISIT 8	02NOV2017	13:16	Y	Double Read
					VISIT 11	10DEC2020	13:52	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S	4_5	Central Disc		Baseline	14AUG2015	14:04	0	Double Read
					VISIT 3A	16NOV2015	11:57	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S	4_5	Central Disc		VISIT 4	04JAN2016	10:05	0	Double Read
					VISIT 6	02MAY2016	10:58	0	Double Read
					VISIT 7	17NOV2016	13:53	0	Double Read
					VISIT 8	02NOV2017	13:16	0	Double Read
					VISIT 11	10DEC2020	13:52	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	14AUG2015	14:04	0	Double Read
					VISIT 3A	16NOV2015	11:57	0	Double Read
					VISIT 4	04JAN2016	10:05	0	Double Read
					VISIT 6	02MAY2016	10:58	0	Double Read
					VISIT 7	17NOV2016	13:53	0	Double Read
					VISIT 8	02NOV2017	13:16	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S	4_5	Caudal Disc		VISIT 11	10DEC2020	13:52	0	Double Read
					Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
Protruding osteophyte (Central Disc)	5_S	4_5	Central Disc		VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52	N	Double Read
					Baseline	14AUG2015	14:04	N	Double Read
					VISIT 3A	16NOV2015	11:57	N	Double Read
					VISIT 4	04JAN2016	10:05	N	Double Read
					VISIT 6	02MAY2016	10:58	N	Double Read
Protruding osteophyte (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 7	17NOV2016	13:53	N	Double Read
					VISIT 8	02NOV2017	13:16	N	Double Read
					VISIT 11	10DEC2020	13:52	N	Double Read
					VISIT 3A	16NOV2015	11:57	N	Double Read
					VISIT 4	04JAN2016	10:05	N	Double Read
					VISIT 6	02MAY2016	10:58	N	Double Read
					VISIT 7	17NOV2016	13:53	N	Double Read
					VISIT 8	02NOV2017	13:16	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 8	02NOV2017	13:16	N	Double Read
					VISIT 11	10DEC2020	13:52	N	Double Read
Relevant scoliosis	5_S	4_5	General		Baseline	14AUG2015	14:04	N	Double Read
					VISIT 3A	16NOV2015	11:57	N	Double Read
					VISIT 4	04JAN2016	10:05	N	Double Read
					VISIT 6	02MAY2016	10:58	N	Double Read
					VISIT 7	17NOV2016	13:53	N	Double Read
					VISIT 8	02NOV2017	13:16	N	Double Read
					VISIT 11	10DEC2020	13:52	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S	4_5	Central Disc		Baseline	14AUG2015	14:04	N	Double Read
					VISIT 3A	16NOV2015	11:57	N	Double Read
					VISIT 4	04JAN2016	10:05	N	Double Read
					VISIT 6	02MAY2016	10:58	N	Double Read
					VISIT 7	17NOV2016	13:53	N	Double Read
					VISIT 8	02NOV2017	13:16	N	Double Read
					VISIT 11	10DEC2020	13:52	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	14AUG2015	14:04	N	Double Read
					VISIT 3A	16NOV2015	11:57	N	Double Read
					VISIT 4	04JAN2016	10:05	N	Double Read
					VISIT 6	02MAY2016	10:58	N	Double Read
					VISIT 7	17NOV2016	13:53	N	Double Read
					VISIT 8	02NOV2017	13:16	N	Double Read
					VISIT 11	10DEC2020	13:52	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	14AUG2015	14:04	61.50384	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	VISIT 3A	16NOV2015	11:57	70.26704	Double Read
					VISIT 4	04JAN2016	10:05	63.61728	Double Read
					VISIT 6	02MAY2016	10:58	90.42544	Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
T2 (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
T2 (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	14AUG2015	14:04	74.14496	Double Read
					VISIT 3A	16NOV2015	11:57	82.43616	Double Read
					VISIT 4	04JAN2016	10:05	77.23408	Double Read
					VISIT 6	02MAY2016	10:58	80.94944	Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S	4_5	Central Disc		Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 8	02NOV2017	13:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		VISIT 11	10DEC2020	13:52		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	14AUG2015	14:04	lower	Double Read
					VISIT 3A	16NOV2015	11:57	lower	Double Read
					VISIT 4	04JAN2016	10:05	lower	Double Read
					VISIT 6	02MAY2016	10:58	equal	Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	14AUG2015	14:04	lower	Double Read
					VISIT 3A	16NOV2015	11:57	lower	Double Read
					VISIT 4	04JAN2016	10:05	lower	Double Read
					VISIT 6	02MAY2016	10:58	lower	Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S	4_5	Central Disc		Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S	4_5	Central Disc		VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	14AUG2015	14:04	15.050110412	Double Read
					VISIT 3A	16NOV2015	11:57	8 6.3275012739	Double Read
					VISIT 4	04JAN2016	10:05	9 9.2293799898	Double Read
					VISIT 6	02MAY2016	10:58	2 22.044980465	Double Read
					VISIT 7	17NOV2016	13:53	4	Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	14AUG2015	14:04	10.9563444879	Double Read
					VISIT 3A	16NOV2015	11:57	6.58324443689	Double Read
					VISIT 4	04JAN2016	10:05	23.401053168	Double Read
					VISIT 6	02MAY2016	10:58	23.1011381009	Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	14AUG2015	14:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	14AUG2015	14:04	15530.5	Double Read
					VISIT 3A	16NOV2015	11:57	16285.5	Double Read
					VISIT 4	04JAN2016	10:05	15115.0	Double Read
					VISIT 6	02MAY2016	10:58	14475.5	Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	VISIT 11	10DEC2020	13:52		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0614 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read
Volume (mm ³) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
Volume (mm ³) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	14AUG2015	14:04	19012.0	Double Read
					VISIT 3A	16NOV2015	11:57	19505.5	Double Read
					VISIT 4	04JAN2016	10:05	19136.0	Double Read
					VISIT 6	02MAY2016	10:58	19033.0	Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
Volume (mm ³) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	14AUG2015	14:04		Double Read
					VISIT 3A	16NOV2015	11:57		Double Read
					VISIT 4	04JAN2016	10:05		Double Read
					VISIT 6	02MAY2016	10:58		Double Read
					VISIT 7	17NOV2016	13:53		Double Read
					VISIT 8	02NOV2017	13:16		Double Read
					VISIT 11	10DEC2020	13:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0615 Age=40 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	21AUG2015	12:25	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5	3_4	Central Disc		Baseline	21AUG2015	12:25	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	21AUG2015	12:25	4	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	21AUG2015	12:25	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5	3_4	Central Disc		Baseline	21AUG2015	12:25	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	21AUG2015	12:25	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	21AUG2015	12:25	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5	3_4	Central Disc		Baseline	21AUG2015	12:25	Y	Double Read
Dorsal disc extrusion (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	21AUG2015	12:25	N	Double Read
Extradiscal fluid collection	4_5	3_4	General		Baseline	21AUG2015	12:25	N	Double Read
Fracture	4_5	3_4	General		Baseline	21AUG2015	12:25	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	21AUG2015	12:25	10.655	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	21AUG2015	12:25	10.93	Double Read
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	21AUG2015	12:25	14.13	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0615 Age=40 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	21AUG2015	12:25	7.046285	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	21AUG2015	12:25	7.121325	Double Read
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	21AUG2015	12:25	11.2971	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	21AUG2015	12:25	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5	3_4	Central Disc		Baseline	21AUG2015	12:25	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	21AUG2015	12:25	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	21AUG2015	12:25	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5	3_4	Central Disc		Baseline	21AUG2015	12:25	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	21AUG2015	12:25	N	Double Read
Normal lordotic LS	4_5	3_4	General		Baseline	21AUG2015	12:25	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	21AUG2015	12:25	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5	3_4	Central Disc		Baseline	21AUG2015	12:25	2	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0615 Age=40 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	21AUG2015	12:25	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	21AUG2015	12:25	N	Double Read
Protruding osteophyte (Central Disc)	4_5	3_4	Central Disc		Baseline	21AUG2015	12:25	N	Double Read
Protruding osteophyte (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	21AUG2015	12:25	N	Double Read
Relevant scoliosis	4_5	3_4	General		Baseline	21AUG2015	12:25	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	21AUG2015	12:25	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5	3_4	Central Disc		Baseline	21AUG2015	12:25	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	21AUG2015	12:25	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5	3_4	Caudal Disc	Anulus Fibrosus	Baseline	21AUG2015	12:25		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	21AUG2015	12:25	74.4208	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5	3_4	Caudal Disc	Nucleus Pulposus	Baseline	21AUG2015	12:25		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5	3_4	Central Disc	Anulus Fibrosus	Baseline	21AUG2015	12:25		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	21AUG2015	12:25	65.49392	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5	3_4	Central Disc	Nucleus Pulposus	Baseline	21AUG2015	12:25		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0615 Age=40 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	3_4	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	21AUG2015	12:25		Double Read
T2 (ms) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	21AUG2015	12:25	63.70016	Double Read
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	3_4	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	21AUG2015	12:25		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5	3_4	Caudal Disc		Baseline	21AUG2015	12:25		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5	3_4	Central Disc		Baseline	21AUG2015	12:25		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	4_5	3_4	Cranial Disc, add. treated		Baseline	21AUG2015	12:25		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5	3_4	Caudal Disc		Baseline	21AUG2015	12:25		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5	3_4	Central Disc		Baseline	21AUG2015	12:25	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, add. treated,)	4_5	3_4	Cranial Disc, add. treated		Baseline	21AUG2015	12:25	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5	3_4	Caudal Disc		Baseline	21AUG2015	12:25		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0615 Age=40 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5	3_4	Central Disc		Baseline	21AUG2015	12:25	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, add. treated,)	4_5	3_4	Cranial Disc, add. treated		Baseline	21AUG2015	12:25	lower	Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5	3_4	Caudal Disc		Baseline	21AUG2015	12:25		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5	3_4	Central Disc		Baseline	21AUG2015	12:25		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, add. treated,)	4_5	3_4	Cranial Disc, add. treated		Baseline	21AUG2015	12:25		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5	3_4	Caudal Disc	Anulus Fibrosus	Baseline	21AUG2015	12:25		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	21AUG2015	12:25	1.7895294717	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5	3_4	Caudal Disc	Nucleus Pulposus	Baseline	21AUG2015	12:25		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5	3_4	Central Disc	Anulus Fibrosus	Baseline	21AUG2015	12:25		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	21AUG2015	12:25	15.916426023	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5	3_4	Central Disc	Nucleus Pulposus	Baseline	21AUG2015	12:25		Double Read
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	3_4	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	21AUG2015	12:25		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0615 Age=40 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	21AUG2015	12:25	8.6445524036	Double Read
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	3_4	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	21AUG2015	12:25		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5	3_4	Caudal Disc	Anulus Fibrosus	Baseline	21AUG2015	12:25		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	21AUG2015	12:25	7927.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5	3_4	Caudal Disc	Nucleus Pulposus	Baseline	21AUG2015	12:25		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5	3_4	Central Disc	Anulus Fibrosus	Baseline	21AUG2015	12:25		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	21AUG2015	12:25	10733.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5	3_4	Central Disc	Nucleus Pulposus	Baseline	21AUG2015	12:25		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	3_4	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	21AUG2015	12:25		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	21AUG2015	12:25	14159.5	Double Read
Volume (mm^3) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	3_4	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	21AUG2015	12:25		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0616 Age=45 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5	5_S	Caudal Disc		Baseline	06NOV2015	12:03	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5	5_S	Central Disc		Baseline	06NOV2015	12:03	2	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	4_5	5_S	Cranial Disc, add. treated		Baseline	06NOV2015	12:03	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5	5_S	Caudal Disc		Baseline	06NOV2015	12:03	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5	5_S	Central Disc		Baseline	06NOV2015	12:03	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	4_5	5_S	Cranial Disc, add. treated		Baseline	06NOV2015	12:03	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5	5_S	Caudal Disc		Baseline	06NOV2015	12:03	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5	5_S	Central Disc		Baseline	06NOV2015	12:03	N	Double Read
Dorsal disc extrusion (Cranial Disc, add. treated)	4_5	5_S	Cranial Disc, add. treated		Baseline	06NOV2015	12:03	N	Double Read
Extradiscal fluid collection	4_5	5_S	General		Baseline	06NOV2015	12:03	N	Double Read
Fracture	4_5	5_S	General		Baseline	06NOV2015	12:03	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5	5_S	Caudal Disc	Complete Disc	Baseline	06NOV2015	12:03	12.585	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5	5_S	Central Disc	Complete Disc	Baseline	06NOV2015	12:03	14.26	Double Read
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	4_5	5_S	Cranial Disc, add. treated	Complete Disc	Baseline	06NOV2015	12:03	13.585	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0616 Age=45 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5	5_S	Caudal Disc	Complete Disc	Baseline	06NOV2015	12:03	8.10322	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5	5_S	Central Disc	Complete Disc	Baseline	06NOV2015	12:03	11.7906	Double Read
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	4_5	5_S	Cranial Disc, add. treated	Complete Disc	Baseline	06NOV2015	12:03	12.5669	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5	5_S	Caudal Disc		Baseline	06NOV2015	12:03	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5	5_S	Central Disc		Baseline	06NOV2015	12:03	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, add. treated)	4_5	5_S	Cranial Disc, add. treated		Baseline	06NOV2015	12:03	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5	5_S	Caudal Disc		Baseline	06NOV2015	12:03	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5	5_S	Central Disc		Baseline	06NOV2015	12:03	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, add. treated)	4_5	5_S	Cranial Disc, add. treated		Baseline	06NOV2015	12:03	N	Double Read
Normal lordotic LS	4_5	5_S	General		Baseline	06NOV2015	12:03	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5	5_S	Caudal Disc		Baseline	06NOV2015	12:03	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5	5_S	Central Disc		Baseline	06NOV2015	12:03	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0616 Age=45 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	4_5	5_S	Cranial Disc, add. treated		Baseline	06NOV2015	12:03	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5	5_S	Caudal Disc		Baseline	06NOV2015	12:03	N	Double Read
Protruding osteophyte (Central Disc)	4_5	5_S	Central Disc		Baseline	06NOV2015	12:03	N	Double Read
Protruding osteophyte (Cranial Disc, add. treated)	4_5	5_S	Cranial Disc, add. treated		Baseline	06NOV2015	12:03	N	Double Read
Relevant scoliosis	4_5	5_S	General		Baseline	06NOV2015	12:03	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5	5_S	Caudal Disc		Baseline	06NOV2015	12:03	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5	5_S	Central Disc		Baseline	06NOV2015	12:03	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	4_5	5_S	Cranial Disc, add. treated		Baseline	06NOV2015	12:03	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5	5_S	Caudal Disc	Anulus Fibrosus	Baseline	06NOV2015	12:03		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5	5_S	Caudal Disc	Complete Disc	Baseline	06NOV2015	12:03	63.21936	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5	5_S	Caudal Disc	Nucleus Pulposus	Baseline	06NOV2015	12:03		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5	5_S	Central Disc	Anulus Fibrosus	Baseline	06NOV2015	12:03		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5	5_S	Central Disc	Complete Disc	Baseline	06NOV2015	12:03	89.79856	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5	5_S	Central Disc	Nucleus Pulposus	Baseline	06NOV2015	12:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0616 Age=45 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	5_S	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	06NOV2015	12:03		Double Read
T2 (ms) (Cranial Disc, add. treated, Complete Disc)	4_5	5_S	Cranial Disc, add. treated	Complete Disc	Baseline	06NOV2015	12:03	87.2448	Double Read
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	5_S	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	06NOV2015	12:03		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5	5_S	Caudal Disc		Baseline	06NOV2015	12:03		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5	5_S	Central Disc		Baseline	06NOV2015	12:03		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	4_5	5_S	Cranial Disc, add. treated		Baseline	06NOV2015	12:03		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5	5_S	Caudal Disc		Baseline	06NOV2015	12:03		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5	5_S	Central Disc		Baseline	06NOV2015	12:03		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, add. treated,)	4_5	5_S	Cranial Disc, add. treated		Baseline	06NOV2015	12:03		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5	5_S	Caudal Disc		Baseline	06NOV2015	12:03	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0616 Age=45 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5	5_S	Central Disc		Baseline	06NOV2015	12:03	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, add. treated,)	4_5	5_S	Cranial Disc, add. treated		Baseline	06NOV2015	12:03		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5	5_S	Caudal Disc		Baseline	06NOV2015	12:03		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5	5_S	Central Disc		Baseline	06NOV2015	12:03		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, add. treated,)	4_5	5_S	Cranial Disc, add. treated		Baseline	06NOV2015	12:03		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5	5_S	Caudal Disc	Anulus Fibrosus	Baseline	06NOV2015	12:03		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5	5_S	Caudal Disc	Complete Disc	Baseline	06NOV2015	12:03	16.6185153728	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5	5_S	Caudal Disc	Nucleus Pulposus	Baseline	06NOV2015	12:03		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5	5_S	Central Disc	Anulus Fibrosus	Baseline	06NOV2015	12:03		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5	5_S	Central Disc	Complete Disc	Baseline	06NOV2015	12:03	10.8714115849	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5	5_S	Central Disc	Nucleus Pulposus	Baseline	06NOV2015	12:03		Double Read
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	5_S	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	06NOV2015	12:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0616 Age=45 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	4_5	5_S	Cranial Disc, add. treated	Complete Disc	Baseline	06NOV2015	12:03	7.49027348394	Double Read
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	5_S	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	06NOV2015	12:03		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5	5_S	Caudal Disc	Anulus Fibrosus	Baseline	06NOV2015	12:03		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5	5_S	Caudal Disc	Complete Disc	Baseline	06NOV2015	12:03	9381.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5	5_S	Caudal Disc	Nucleus Pulposus	Baseline	06NOV2015	12:03		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5	5_S	Central Disc	Anulus Fibrosus	Baseline	06NOV2015	12:03		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5	5_S	Central Disc	Complete Disc	Baseline	06NOV2015	12:03	15015.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5	5_S	Central Disc	Nucleus Pulposus	Baseline	06NOV2015	12:03		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	5_S	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	06NOV2015	12:03		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Complete Disc)	4_5	5_S	Cranial Disc, add. treated	Complete Disc	Baseline	06NOV2015	12:03	16066.0	Double Read
Volume (mm^3) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	5_S	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	06NOV2015	12:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0617 Age=33 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	21DEC2015	15:01	2	Double Read
					VISIT 3A	08MAR2016	7:40	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5	3_4	Central Disc		Baseline	21DEC2015	15:01	3	Double Read
					VISIT 3A	08MAR2016	7:40	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	21DEC2015	15:01	3	Double Read
					VISIT 3A	08MAR2016	7:40	4	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	21DEC2015	15:01	N	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5	3_4	Central Disc		Baseline	21DEC2015	15:01	N	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	21DEC2015	15:01	N	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	21DEC2015	15:01	N	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5	3_4	Central Disc		Baseline	21DEC2015	15:01	Y	Double Read
					VISIT 3A	08MAR2016	7:40	Y	Double Read
Dorsal disc extrusion (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	21DEC2015	15:01	Y	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read
Extradiscal fluid collection	4_5	3_4	General		Baseline	21DEC2015	15:01	N	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read
Fracture	4_5	3_4	General		Baseline	21DEC2015	15:01	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0617 Age=33 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Fracture	4_5	3_4	General		VISIT 3A	08MAR2016	7:40	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	21DEC2015	15:01	12.305	Double Read
					VISIT 3A	08MAR2016	7:40	13.795	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	21DEC2015	15:01	12.665	Double Read
					VISIT 3A	08MAR2016	7:40	14.015	Double Read
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	21DEC2015	15:01	12.935	Double Read
					VISIT 3A	08MAR2016	7:40	13.285	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	21DEC2015	15:01	9.19027	Double Read
					VISIT 3A	08MAR2016	7:40	10.321	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	21DEC2015	15:01	10.185515	Double Read
					VISIT 3A	08MAR2016	7:40	8.92667	Double Read
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	21DEC2015	15:01	10.134265	Double Read
					VISIT 3A	08MAR2016	7:40	12.5961	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	21DEC2015	15:01	N	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5	3_4	Central Disc		Baseline	21DEC2015	15:01	N	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0617 Age=33 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	21DEC2015	15:01	N	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	21DEC2015	15:01	N	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5	3_4	Central Disc		Baseline	21DEC2015	15:01	N	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	21DEC2015	15:01	N	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read
Normal lordotic LS	4_5	3_4	General		Baseline	21DEC2015	15:01	Y	Double Read
					VISIT 3A	08MAR2016	7:40	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	21DEC2015	15:01	0	Double Read
					VISIT 3A	08MAR2016	7:40	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5	3_4	Central Disc		Baseline	21DEC2015	15:01	0	Double Read
					VISIT 3A	08MAR2016	7:40	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	21DEC2015	15:01	0	Double Read
					VISIT 3A	08MAR2016	7:40	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	21DEC2015	15:01	N	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read
Protruding osteophyte (Central Disc)	4_5	3_4	Central Disc		Baseline	21DEC2015	15:01	N	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0617 Age=33 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	21DEC2015	15:01	N	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read
Relevant scoliosis	4_5	3_4	General		Baseline	21DEC2015	15:01	N	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	21DEC2015	15:01	N	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5	3_4	Central Disc		Baseline	21DEC2015	15:01	N	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	21DEC2015	15:01	N	Double Read
					VISIT 3A	08MAR2016	7:40	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5	3_4	Caudal Disc	Anulus Fibrosus	Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	21DEC2015	15:01	75.10848	Double Read
					VISIT 3A	08MAR2016	7:40	81.70224	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5	3_4	Caudal Disc	Nucleus Pulposus	Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5	3_4	Central Disc	Anulus Fibrosus	Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	21DEC2015	15:01	75.7096	Double Read
					VISIT 3A	08MAR2016	7:40	81.80864	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0617 Age=33 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5	3_4	Central Disc	Nucleus Pulposus	Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
T2 (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	3_4	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
T2 (ms) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	21DEC2015	15:01	70.87104	Double Read
					VISIT 3A	08MAR2016	7:40	76.10112	Double Read
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	3_4	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5	3_4	Caudal Disc		Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5	3_4	Central Disc		Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	4_5	3_4	Cranial Disc, add. treated		Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5	3_4	Caudal Disc		Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0617 Age=33 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5	3_4	Central Disc		Baseline	21DEC2015	15:01	lower	Double Read
					VISIT 3A	08MAR2016	7:40	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, add. treated,)	4_5	3_4	Cranial Disc, add. treated		Baseline	21DEC2015	15:01	equal	Double Read
					VISIT 3A	08MAR2016	7:40	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5	3_4	Caudal Disc		Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5	3_4	Central Disc		Baseline	21DEC2015	15:01	lower	Double Read
					VISIT 3A	08MAR2016	7:40	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, add. treated,)	4_5	3_4	Cranial Disc, add. treated		Baseline	21DEC2015	15:01	lower	Double Read
					VISIT 3A	08MAR2016	7:40	lower	Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5	3_4	Caudal Disc		Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5	3_4	Central Disc		Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, add. treated,)	4_5	3_4	Cranial Disc, add. treated		Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0617 Age=33 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5	3_4	Caudal Disc	Anulus Fibrosus	Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	21DEC2015	15:01	4.8770375403	Double Read
					VISIT 3A	08MAR2016	7:40	10.2501851537	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5	3_4	Caudal Disc	Nucleus Pulposus	Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5	3_4	Central Disc	Anulus Fibrosus	Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	21DEC2015	15:01	3.0081671479	Double Read
					VISIT 3A	08MAR2016	7:40	12.2812977748	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5	3_4	Central Disc	Nucleus Pulposus	Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	3_4	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	21DEC2015	15:01	7.7726448106	Double Read
					VISIT 3A	08MAR2016	7:40	11.0521623917	Double Read
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	3_4	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0617 Age=33 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5	3_4	Caudal Disc	Anulus Fibrosus	Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	21DEC2015	15:01	11734.5	Double Read
					VISIT 3A	08MAR2016	7:40	13835.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5	3_4	Caudal Disc	Nucleus Pulposus	Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5	3_4	Central Disc	Anulus Fibrosus	Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	21DEC2015	15:01	14988.5	Double Read
					VISIT 3A	08MAR2016	7:40	16867.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5	3_4	Central Disc	Nucleus Pulposus	Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	3_4	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	21DEC2015	15:01	16252.0	Double Read
					VISIT 3A	08MAR2016	7:40	18447.5	Double Read
Volume (mm^3) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	3_4	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	21DEC2015	15:01		Double Read
					VISIT 3A	08MAR2016	7:40		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0618 Age=36 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	14JAN2016	11:21		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	14JAN2016	11:21	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JAN2016	11:21	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	14JAN2016	11:21		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	14JAN2016	11:21	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JAN2016	11:21	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	14JAN2016	11:21		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	14JAN2016	11:21	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JAN2016	11:21	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	14JAN2016	11:21	N	Double Read
Fracture	5_S		General		Baseline	14JAN2016	11:21	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JAN2016	11:21		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JAN2016	11:21	12.39	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JAN2016	11:21	14.945	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0618 Age=36 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JAN2016	11:21		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JAN2016	11:21	7.253465	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JAN2016	11:21	12.57415	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	14JAN2016	11:21		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	14JAN2016	11:21	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JAN2016	11:21	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	14JAN2016	11:21		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	14JAN2016	11:21	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JAN2016	11:21	N	Double Read
Normal lordotic LS	5_S		General		Baseline	14JAN2016	11:21	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	14JAN2016	11:21		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	14JAN2016	11:21	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0618 Age=36 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JAN2016	11:21	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	14JAN2016	11:21		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	14JAN2016	11:21	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JAN2016	11:21	N	Double Read
Relevant scoliosis	5_S		General		Baseline	14JAN2016	11:21	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	14JAN2016	11:21		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	14JAN2016	11:21	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	14JAN2016	11:21	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	14JAN2016	11:21		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JAN2016	11:21		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	14JAN2016	11:21		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	14JAN2016	11:21		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JAN2016	11:21	67.34144	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	14JAN2016	11:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0618 Age=36 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JAN2016	11:21		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JAN2016	11:21	105.2832	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	14JAN2016	11:21		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JAN2016	11:21		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	14JAN2016	11:21		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JAN2016	11:21		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JAN2016	11:21		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	14JAN2016	11:21		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JAN2016	11:21		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JAN2016	11:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0618 Age=36 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	14JAN2016	11:21	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JAN2016	11:21		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	14JAN2016	11:21		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	14JAN2016	11:21		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	14JAN2016	11:21		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	14JAN2016	11:21		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JAN2016	11:21		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	14JAN2016	11:21		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	14JAN2016	11:21		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JAN2016	11:21	4.83735688806	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	14JAN2016	11:21		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JAN2016	11:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0618 Age=36 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JAN2016	11:21	3.53320876507	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	14JAN2016	11:21		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	14JAN2016	11:21		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	14JAN2016	11:21		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	14JAN2016	11:21		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	14JAN2016	11:21		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	14JAN2016	11:21	10333.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	14JAN2016	11:21		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JAN2016	11:21		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	14JAN2016	11:21	15158.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	14JAN2016	11:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	22FEB2016	13:39	4	Double Read
					VISIT 3A	09MAY2016	13:27	4	Double Read
					VISIT 4	20JUN2016	14:28	4	Double Read
					VISIT 6	03NOV2016	15:23	4	Double Read
					VISIT 7	15MAY2017	12:38	4	Double Read
					VISIT 8	02MAY2018	12:35	4	Double Read
					VISIT 11	28MAY2021	11:10	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	22FEB2016	13:39	3	Double Read
					VISIT 3A	09MAY2016	13:27	3	Double Read
					VISIT 4	20JUN2016	14:28	3	Double Read
					VISIT 6	03NOV2016	15:23	3	Double Read
					VISIT 7	15MAY2017	12:38	3	Double Read
					VISIT 8	02MAY2018	12:35	3	Double Read
					VISIT 11	28MAY2021	11:10	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	22FEB2016	13:39	4	Double Read
					VISIT 3A	09MAY2016	13:27	4	Double Read
					VISIT 4	20JUN2016	14:28	4	Double Read
					VISIT 6	03NOV2016	15:23	4	Double Read
					VISIT 7	15MAY2017	12:38	4	Double Read
					VISIT 8	02MAY2018	12:35	4	Double Read
					VISIT 11	28MAY2021	11:10	4	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	22FEB2016	13:39	N	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	N	Double Read
					VISIT 6	03NOV2016	15:23	N	Double Read
					VISIT 7	15MAY2017	12:38	N	Double Read
					VISIT 8	02MAY2018	12:35	N	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	22FEB2016	13:39	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	N	Double Read
					VISIT 6	03NOV2016	15:23	N	Double Read
					VISIT 7	15MAY2017	12:38	N	Double Read
					VISIT 8	02MAY2018	12:35	N	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	22FEB2016	13:39	N	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	N	Double Read
					VISIT 6	03NOV2016	15:23	N	Double Read
					VISIT 7	15MAY2017	12:38	N	Double Read
					VISIT 8	02MAY2018	12:35	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 11	28MAY2021	11:10	N	Double Read
					Baseline	22FEB2016	13:39	N	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	N	Double Read
					VISIT 6	03NOV2016	15:23	N	Double Read
					VISIT 7	15MAY2017	12:38	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		VISIT 8	02MAY2018	12:35	N	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
					Baseline	22FEB2016	13:39	Y	Double Read
					VISIT 3A	09MAY2016	13:27	Y	Double Read
					VISIT 4	20JUN2016	14:28	N	Double Read
					VISIT 6	03NOV2016	15:23	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	15MAY2017	12:38	N	Double Read
					VISIT 8	02MAY2018	12:35	Y	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
					Baseline	22FEB2016	13:39	N	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	N	Double Read
					VISIT 6	03NOV2016	15:23	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	15MAY2017	12:38	N	Double Read
					VISIT 8	02MAY2018	12:35	N	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	22FEB2016	13:39	N	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	N	Double Read
					VISIT 6	03NOV2016	15:23	N	Double Read
					VISIT 7	15MAY2017	12:38	N	Double Read
					VISIT 8	02MAY2018	12:35	N	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
Fracture	4_5		General		Baseline	22FEB2016	13:39	N	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	N	Double Read
					VISIT 6	03NOV2016	15:23	N	Double Read
					VISIT 7	15MAY2017	12:38	N	Double Read
					VISIT 8	02MAY2018	12:35	N	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	22FEB2016	13:39	19.87	Double Read
					VISIT 3A	09MAY2016	13:27	19.735	Double Read
					VISIT 4	20JUN2016	14:28	20.67	Double Read
					VISIT 6	03NOV2016	15:23	20.36	Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	22FEB2016	13:39	16.975	Double Read
					VISIT 3A	09MAY2016	13:27	16.78	Double Read
					VISIT 4	20JUN2016	14:28	18.045	Double Read
					VISIT 6	03NOV2016	15:23	16.835	Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	22FEB2016	13:39	16.515	Double Read
					VISIT 3A	09MAY2016	13:27	17.73	Double Read
					VISIT 4	20JUN2016	14:28	17.92	Double Read
					VISIT 6	03NOV2016	15:23	19.365	Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	22FEB2016	13:39	8.663285	Double Read
					VISIT 3A	09MAY2016	13:27	7.47058	Double Read
					VISIT 4	20JUN2016	14:28	9.60424	Double Read
					VISIT 6	03NOV2016	15:23	7.663075	Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35	9.685255	Double Read
					VISIT 11	28MAY2021	11:10	9.61094	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	22FEB2016	13:39	9.653495	Double Read
					VISIT 3A	09MAY2016	13:27	9.668535	Double Read
					VISIT 4	20JUN2016	14:28	8.13432	Double Read
					VISIT 6	03NOV2016	15:23	7.396825	Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35	9.818065	Double Read
					VISIT 11	28MAY2021	11:10	8.704615	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	22FEB2016	13:39	8.944175	Double Read
					VISIT 3A	09MAY2016	13:27	9.571355	Double Read
					VISIT 4	20JUN2016	14:28	8.05395	Double Read
					VISIT 6	03NOV2016	15:23	7.65724	Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35	8.800895	Double Read
					VISIT 11	28MAY2021	11:10	8.82256	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	22FEB2016	13:39	Y	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	Y	Double Read
					VISIT 6	03NOV2016	15:23	Y	Double Read
					VISIT 7	15MAY2017	12:38	Y	Double Read
					VISIT 8	02MAY2018	12:35	Y	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	22FEB2016	13:39	Y	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	N	Double Read
					VISIT 6	03NOV2016	15:23	Y	Double Read
					VISIT 7	15MAY2017	12:38	Y	Double Read
					VISIT 8	02MAY2018	12:35	Y	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	22FEB2016	13:39	N	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	N	Double Read
					VISIT 6	03NOV2016	15:23	N	Double Read
					VISIT 7	15MAY2017	12:38	N	Double Read
					VISIT 8	02MAY2018	12:35	N	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	22FEB2016	13:39	N	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	N	Double Read
					VISIT 6	03NOV2016	15:23	N	Double Read
					VISIT 7	15MAY2017	12:38	N	Double Read
					VISIT 8	02MAY2018	12:35	N	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	22FEB2016	13:39	N	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	Y	Double Read
					VISIT 6	03NOV2016	15:23	N	Double Read
					VISIT 7	15MAY2017	12:38	N	Double Read
					VISIT 8	02MAY2018	12:35	N	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	22FEB2016	13:39	N	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	N	Double Read
					VISIT 6	03NOV2016	15:23	N	Double Read
					VISIT 7	15MAY2017	12:38	N	Double Read
					VISIT 8	02MAY2018	12:35	N	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
Normal lordotic LS	4_5		General		Baseline	22FEB2016	13:39	N	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	N	Double Read
					VISIT 6	03NOV2016	15:23	N	Double Read
					VISIT 7	15MAY2017	12:38	N	Double Read
					VISIT 8	02MAY2018	12:35	N	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	22FEB2016	13:39	0	Double Read
					VISIT 3A	09MAY2016	13:27	0	Double Read
					VISIT 4	20JUN2016	14:28	0	Double Read
					VISIT 6	03NOV2016	15:23	0	Double Read
					VISIT 7	15MAY2017	12:38	0	Double Read
					VISIT 8	02MAY2018	12:35	0	Double Read
					VISIT 11	28MAY2021	11:10	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	22FEB2016	13:39	0	Double Read
					VISIT 3A	09MAY2016	13:27	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 4	20JUN2016	14:28	0	Double Read
					VISIT 6	03NOV2016	15:23	0	Double Read
					VISIT 7	15MAY2017	12:38	0	Double Read
					VISIT 8	02MAY2018	12:35	0	Double Read
					VISIT 11	28MAY2021	11:10	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	22FEB2016	13:39	0	Double Read
					VISIT 3A	09MAY2016	13:27	0	Double Read
					VISIT 4	20JUN2016	14:28	0	Double Read
					VISIT 6	03NOV2016	15:23	0	Double Read
					VISIT 7	15MAY2017	12:38	0	Double Read
					VISIT 8	02MAY2018	12:35	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 11	28MAY2021	11:10	0	Double Read
					Baseline	22FEB2016	13:39	N	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	Y	Double Read
					VISIT 6	03NOV2016	15:23	Y	Double Read
					VISIT 7	15MAY2017	12:38	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	02MAY2018	12:35	N	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
					Baseline	22FEB2016	13:39	N	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	Y	Double Read
					VISIT 6	03NOV2016	15:23	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	15MAY2017	12:38	N	Double Read
					VISIT 8	02MAY2018	12:35	N	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
					Baseline	22FEB2016	13:39	N	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	N	Double Read
					VISIT 6	03NOV2016	15:23	N	Double Read
					VISIT 7	15MAY2017	12:38	N	Double Read
					VISIT 8	02MAY2018	12:35	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	02MAY2018	12:35	N	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
Relevant scoliosis	4_5		General		Baseline	22FEB2016	13:39	N	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	N	Double Read
					VISIT 6	03NOV2016	15:23	N	Double Read
					VISIT 7	15MAY2017	12:38	N	Double Read
					VISIT 8	02MAY2018	12:35	N	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	22FEB2016	13:39	N	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	N	Double Read
					VISIT 6	03NOV2016	15:23	N	Double Read
					VISIT 7	15MAY2017	12:38	N	Double Read
					VISIT 8	02MAY2018	12:35	N	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	22FEB2016	13:39	N	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	N	Double Read
					VISIT 6	03NOV2016	15:23	N	Double Read
					VISIT 7	15MAY2017	12:38	N	Double Read
					VISIT 8	02MAY2018	12:35	N	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	22FEB2016	13:39	N	Double Read
					VISIT 3A	09MAY2016	13:27	N	Double Read
					VISIT 4	20JUN2016	14:28	N	Double Read
					VISIT 6	03NOV2016	15:23	N	Double Read
					VISIT 7	15MAY2017	12:38	N	Double Read
					VISIT 8	02MAY2018	12:35	N	Double Read
					VISIT 11	28MAY2021	11:10	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	22FEB2016	13:39	50.765904	Double Read
					VISIT 3A	09MAY2016	13:27	62.52944	Double Read
					VISIT 4	20JUN2016	14:28	68.62064	Double Read
					VISIT 6	03NOV2016	15:23	61.73728	Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35	68.09408	Double Read
					VISIT 11	28MAY2021	11:10	62.3224	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	22FEB2016	13:39	67.3832	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	09MAY2016	13:27	71.66928	Double Read
					VISIT 4	20JUN2016	14:28	79.97696	Double Read
					VISIT 6	03NOV2016	15:23	76.30512	Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35	72.79552	Double Read
					VISIT 11	28MAY2021	11:10	79.19616	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	22FEB2016	13:39	55.2544	Double Read
					VISIT 3A	09MAY2016	13:27	65.65696	Double Read
					VISIT 4	20JUN2016	14:28	71.87024	Double Read
					VISIT 6	03NOV2016	15:23	69.63664	Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35	65.23168	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	28MAY2021	11:10	62.5056	Double Read
					VISIT 3A	09MAY2016	13:27		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	22FEB2016	13:39	higher	Double Read
					VISIT 3A	09MAY2016	13:27	higher	Double Read
					VISIT 4	20JUN2016	14:28	higher	Double Read
					VISIT 6	03NOV2016	15:23	higher	Double Read
					VISIT 7	15MAY2017	12:38	higher	Double Read
					VISIT 8	02MAY2018	12:35	higher	Double Read
					VISIT 11	28MAY2021	11:10	higher	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 8	02MAY2018	12:35		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		VISIT 11	28MAY2021	11:10		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	22FEB2016	13:39	higher	Double Read
					VISIT 3A	09MAY2016	13:27	higher	Double Read
					VISIT 4	20JUN2016	14:28	higher	Double Read
					VISIT 6	03NOV2016	15:23	higher	Double Read
					VISIT 7	15MAY2017	12:38	higher	Double Read
					VISIT 8	02MAY2018	12:35	higher	Double Read
					VISIT 11	28MAY2021	11:10	higher	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	22FEB2016	13:39	6.8572108034	Double Read
					VISIT 3A	09MAY2016	13:27	12.579602514	Double Read
					VISIT 4	20JUN2016	14:28	14.945133344	Double Read
					VISIT 6	03NOV2016	15:23	13.223998641	Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35	16.158790555	Double Read
					VISIT 11	28MAY2021	11:10	16.173127229	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	22FEB2016	13:39	14.495192797	Double Read
					VISIT 3A	09MAY2016	13:27	13.622877526	Double Read
					VISIT 4	20JUN2016	14:28	16.843757431	Double Read
					VISIT 6	03NOV2016	15:23	19.771632410	Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35	16.378393069	Double Read
					VISIT 11	28MAY2021	11:10	19.305045014	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	22FEB2016	13:39	12.0062510617	Double Read
					VISIT 3A	09MAY2016	13:27	14.0818753185	Double Read
					VISIT 4	20JUN2016	14:28	16.138882283	Double Read
					VISIT 6	03NOV2016	15:23	14.8135960591	Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35	13.2291625615	Double Read
					VISIT 11	28MAY2021	11:10	15.9398675047	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27	25096.5	Double Read
					VISIT 4	20JUN2016	14:28	25229.0	Double Read
					VISIT 6	03NOV2016	15:23	24559.5	Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27	24805.0	Double Read
					VISIT 4	20JUN2016	14:28	26883.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 6	03NOV2016	15:23	25702.5	Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	VISIT 11	28MAY2021	11:10		Double Read
					Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read
					VISIT 7	15MAY2017	12:38		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
					Baseline	22FEB2016	13:39	25304.0	Double Read
					VISIT 3A	09MAY2016	13:27	28122.0	Double Read
					VISIT 4	20JUN2016	14:28	28803.5	Double Read
					VISIT 6	03NOV2016	15:23	28401.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read
					Baseline	22FEB2016	13:39		Double Read
					VISIT 3A	09MAY2016	13:27		Double Read
					VISIT 4	20JUN2016	14:28		Double Read
					VISIT 6	03NOV2016	15:23		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0619 Age=55 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 7	15MAY2017	12:38		Double Read
					VISIT 8	02MAY2018	12:35		Double Read
					VISIT 11	28MAY2021	11:10		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0620 Age=27 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S	4_5	Central Disc		Baseline	22FEB2016	15:16	3	Double Read
					VISIT 4	12APR2016	14:23	4	Double Read
					VISIT 6	17AUG2016	9:54	3	Double Read
					VISIT 7	20FEB2017	11:17	4	Double Read
					VISIT 8	26MAR2018	13:32	3	Double Read
					VISIT 11	02MAR2021	13:16	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22FEB2016	15:16	1	Double Read
					VISIT 4	12APR2016	14:23	2	Double Read
					VISIT 6	17AUG2016	9:54	2	Double Read
					VISIT 7	20FEB2017	11:17	2	Double Read
					VISIT 8	26MAR2018	13:32	2	Double Read
					VISIT 11	02MAR2021	13:16	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S	4_5	Central Disc		Baseline	22FEB2016	15:16	N	Double Read
					VISIT 4	12APR2016	14:23	N	Double Read
					VISIT 6	17AUG2016	9:54	N	Double Read
					VISIT 7	20FEB2017	11:17	N	Double Read
					VISIT 8	26MAR2018	13:32	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0620 Age=27 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S	4_5	Central Disc		VISIT 11	02MAR2021	13:16	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22FEB2016	15:16	N	Double Read
					VISIT 4	12APR2016	14:23	N	Double Read
					VISIT 6	17AUG2016	9:54	N	Double Read
					VISIT 7	20FEB2017	11:17	N	Double Read
					VISIT 8	26MAR2018	13:32	N	Double Read
					VISIT 11	02MAR2021	13:16	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
Dorsal disc extrusion (Central Disc)	5_S	4_5	Central Disc		Baseline	22FEB2016	15:16	Y	Double Read
					VISIT 4	12APR2016	14:23	Y	Double Read
					VISIT 6	17AUG2016	9:54	Y	Double Read
					VISIT 7	20FEB2017	11:17	Y	Double Read
					VISIT 8	26MAR2018	13:32	N	Double Read
					VISIT 11	02MAR2021	13:16	Y	Double Read
Dorsal disc extrusion (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22FEB2016	15:16	N	Double Read
					VISIT 4	12APR2016	14:23	N	Double Read
					VISIT 6	17AUG2016	9:54	N	Double Read
					VISIT 7	20FEB2017	11:17	N	Double Read
					VISIT 8	26MAR2018	13:32	N	Double Read
					VISIT 11	02MAR2021	13:16	N	Double Read
Extradiscal fluid collection	5_S	4_5	General		Baseline	22FEB2016	15:16	N	Double Read
					VISIT 4	12APR2016	14:23	N	Double Read
					VISIT 6	17AUG2016	9:54	N	Double Read
					VISIT 7	20FEB2017	11:17	N	Double Read
					VISIT 8	26MAR2018	13:32	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0620 Age=27 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S	4_5	General		VISIT 11	02MAR2021	13:16	N	Double Read
Fracture	5_S	4_5	General		Baseline	22FEB2016	15:16	N	Double Read
					VISIT 4	12APR2016	14:23	N	Double Read
					VISIT 6	17AUG2016	9:54	N	Double Read
					VISIT 7	20FEB2017	11:17	N	Double Read
					VISIT 8	26MAR2018	13:32	N	Double Read
					VISIT 11	02MAR2021	13:16	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	22FEB2016	15:16	15.045	Double Read
					VISIT 4	12APR2016	14:23	15.14	Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17	16.88	Double Read
					VISIT 8	26MAR2018	13:32	15.505	Double Read
					VISIT 11	02MAR2021	13:16	15.64	Double Read
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	22FEB2016	15:16	13.315	Double Read
					VISIT 4	12APR2016	14:23	14.96	Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17	17.255	Double Read
					VISIT 8	26MAR2018	13:32	15.34	Double Read
					VISIT 11	02MAR2021	13:16	15.685	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0620 Age=27 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	22FEB2016	15:16	9.073985	Double Read
					VISIT 4	12APR2016	14:23	11.0516	Double Read
					VISIT 6	17AUG2016	9:54	8.60653	Double Read
					VISIT 7	20FEB2017	11:17	9.56653	Double Read
					VISIT 8	26MAR2018	13:32	8.884015	Double Read
					VISIT 11	02MAR2021	13:16	9.668435	Double Read
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	22FEB2016	15:16	10.3522	Double Read
					VISIT 4	12APR2016	14:23	11.7716	Double Read
					VISIT 6	17AUG2016	9:54	9.616745	Double Read
					VISIT 7	20FEB2017	11:17	11.3037	Double Read
					VISIT 8	26MAR2018	13:32	10.40596	Double Read
					VISIT 11	02MAR2021	13:16	11.2062	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S	4_5	Central Disc		Baseline	22FEB2016	15:16	N	Double Read
					VISIT 4	12APR2016	14:23	N	Double Read
					VISIT 6	17AUG2016	9:54	N	Double Read
					VISIT 7	20FEB2017	11:17	N	Double Read
					VISIT 8	26MAR2018	13:32	N	Double Read
					VISIT 11	02MAR2021	13:16	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0620 Age=27 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22FEB2016	15:16	N	Double Read
					VISIT 4	12APR2016	14:23	N	Double Read
					VISIT 6	17AUG2016	9:54	N	Double Read
					VISIT 7	20FEB2017	11:17	N	Double Read
					VISIT 8	26MAR2018	13:32	N	Double Read
					VISIT 11	02MAR2021	13:16	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S	4_5	Central Disc		Baseline	22FEB2016	15:16	N	Double Read
					VISIT 4	12APR2016	14:23	N	Double Read
					VISIT 6	17AUG2016	9:54	N	Double Read
					VISIT 7	20FEB2017	11:17	N	Double Read
					VISIT 8	26MAR2018	13:32	N	Double Read
					VISIT 11	02MAR2021	13:16	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22FEB2016	15:16	N	Double Read
					VISIT 4	12APR2016	14:23	N	Double Read
					VISIT 6	17AUG2016	9:54	N	Double Read
					VISIT 7	20FEB2017	11:17	N	Double Read
					VISIT 8	26MAR2018	13:32	N	Double Read
					VISIT 11	02MAR2021	13:16	N	Double Read
Normal lordotic LS	5_S	4_5	General		Baseline	22FEB2016	15:16	Y	Double Read
					VISIT 4	12APR2016	14:23	Y	Double Read
					VISIT 6	17AUG2016	9:54	Y	Double Read
					VISIT 7	20FEB2017	11:17	Y	Double Read
					VISIT 8	26MAR2018	13:32	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0620 Age=27 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	5_S	4_5	General		VISIT 11	02MAR2021	13:16	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S	4_5	Central Disc		VISIT 11	02MAR2021	13:16		Double Read
					Baseline	22FEB2016	15:16	0	Double Read
					VISIT 4	12APR2016	14:23	0	Double Read
					VISIT 6	17AUG2016	9:54	0	Double Read
					VISIT 7	20FEB2017	11:17	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 8	26MAR2018	13:32	0	Double Read
					VISIT 11	02MAR2021	13:16	0	Double Read
					Baseline	22FEB2016	15:16	0	Double Read
					VISIT 4	12APR2016	14:23	0	Double Read
					VISIT 6	17AUG2016	9:54	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S	4_5	Caudal Disc		VISIT 7	20FEB2017	11:17	0	Double Read
					VISIT 8	26MAR2018	13:32	0	Double Read
					VISIT 11	02MAR2021	13:16	0	Double Read
					Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
Protruding osteophyte (Central Disc)	5_S	4_5	Central Disc		VISIT 6	17AUG2016	9:54	N	Double Read
					VISIT 7	20FEB2017	11:17	N	Double Read
					VISIT 8	26MAR2018	13:32	N	Double Read
					Baseline	22FEB2016	15:16	N	Double Read
					VISIT 4	12APR2016	14:23	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0620 Age=27 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S	4_5	Central Disc		VISIT 11	02MAR2021	13:16	N	Double Read
Protruding osteophyte (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22FEB2016	15:16	N	Double Read
					VISIT 4	12APR2016	14:23	N	Double Read
					VISIT 6	17AUG2016	9:54	N	Double Read
					VISIT 7	20FEB2017	11:17	N	Double Read
					VISIT 8	26MAR2018	13:32	N	Double Read
					VISIT 11	02MAR2021	13:16	N	Double Read
Relevant scoliosis	5_S	4_5	General		Baseline	22FEB2016	15:16	N	Double Read
					VISIT 4	12APR2016	14:23	N	Double Read
					VISIT 6	17AUG2016	9:54	N	Double Read
					VISIT 7	20FEB2017	11:17	N	Double Read
					VISIT 8	26MAR2018	13:32	N	Double Read
					VISIT 11	02MAR2021	13:16	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S	4_5	Central Disc		Baseline	22FEB2016	15:16	N	Double Read
					VISIT 4	12APR2016	14:23	N	Double Read
					VISIT 6	17AUG2016	9:54	N	Double Read
					VISIT 7	20FEB2017	11:17	N	Double Read
					VISIT 8	26MAR2018	13:32	N	Double Read
					VISIT 11	02MAR2021	13:16	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	22FEB2016	15:16	N	Double Read
					VISIT 4	12APR2016	14:23	N	Double Read
					VISIT 6	17AUG2016	9:54	N	Double Read
					VISIT 7	20FEB2017	11:17	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0620 Age=27 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 8	26MAR2018	13:32	N	Double Read
					VISIT 11	02MAR2021	13:16	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	22FEB2016	15:16	63.14144	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0620 Age=27 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	VISIT 4	12APR2016	14:23	74.53008	Double Read
					VISIT 6	17AUG2016	9:54	92.67296	Double Read
					VISIT 7	20FEB2017	11:17	71.5072	Double Read
					VISIT 8	26MAR2018	13:32	74.132	Double Read
					VISIT 11	02MAR2021	13:16	64.3096	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
T2 (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
T2 (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	22FEB2016	15:16	100.63168	Double Read
					VISIT 4	12APR2016	14:23	103.89824	Double Read
					VISIT 6	17AUG2016	9:54	115.96016	Double Read
					VISIT 7	20FEB2017	11:17	109.6824	Double Read
					VISIT 8	26MAR2018	13:32	107.1736	Double Read
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	VISIT 11	02MAR2021	13:16	102.32032	Double Read
					Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0620 Age=27 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S	4_5	Central Disc		Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0620 Age=27 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16	higher	Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	22FEB2016	15:16	lower	Double Read
					VISIT 4	12APR2016	14:23	lower	Double Read
					VISIT 6	17AUG2016	9:54	lower	Double Read
					VISIT 7	20FEB2017	11:17	lower	Double Read
					VISIT 8	26MAR2018	13:32	lower	Double Read
					VISIT 11	02MAR2021	13:16	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0620 Age=27 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	22FEB2016	15:16	equal	Double Read
					VISIT 4	12APR2016	14:23	equal	Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32	equal	Double Read
					VISIT 11	02MAR2021	13:16	equal	Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S	4_5	Central Disc		Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0620 Age=27 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	22FEB2016	15:16	7.22804144726	Double Read
					VISIT 4	12APR2016	14:23	19.7789706132	Double Read
					VISIT 6	17AUG2016	9:54	21.4277560727	Double Read
					VISIT 7	20FEB2017	11:17	11.7954815696	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0620 Age=27 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	VISIT 8	26MAR2018	13:32	14.0201324953	Double Read
					VISIT 11	02MAR2021	13:16	13.6314591472	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	22FEB2016	15:16	6.22841515203	Double Read
					VISIT 4	12APR2016	14:23	30.857958213	Double Read
					VISIT 6	17AUG2016	9:54	48.2299303551	Double Read
					VISIT 7	20FEB2017	11:17	44.3893324273	Double Read
					VISIT 8	26MAR2018	13:32	35.4736198403	Double Read
					VISIT 11	02MAR2021	13:16	39.4013249532	Double Read
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0620 Age=27 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	22FEB2016	15:16	14000.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=06/0620 Age=27 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	VISIT 4	12APR2016	14:23	16134.5	Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17	16882.0	Double Read
					VISIT 8	26MAR2018	13:32	16504.0	Double Read
					VISIT 11	02MAR2021	13:16	15296.0	Double Read
Volume (mm ³) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
Volume (mm ³) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
Volume (mm ³) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	22FEB2016	15:16	15848.5	Double Read
					VISIT 4	12APR2016	14:23	19263.0	Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17	19619.5	Double Read
					VISIT 8	26MAR2018	13:32	17547.0	Double Read
Volume (mm ³) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	22FEB2016	15:16		Double Read
					VISIT 4	12APR2016	14:23		Double Read
					VISIT 6	17AUG2016	9:54		Double Read
					VISIT 7	20FEB2017	11:17		Double Read
					VISIT 8	26MAR2018	13:32		Double Read
					VISIT 11	02MAR2021	13:16	18569.5	Double Read
					VISIT 11	02MAR2021	13:16		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
					VISIT 11	02MAR2021	13:16		Double Read
					VISIT 11	02MAR2021	13:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	04NOV2014	8:07	3	Double Read
					VISIT 3A	19JAN2015	10:20	4	Double Read
					VISIT 4	04MAR2015	10:09	3	Double Read
					VISIT 6	20JUL2015	10:14	4	Double Read
					VISIT 7	14JAN2016	10:16	4	Double Read
					VISIT 8	30JAN2017	10:28	4	Double Read
					VISIT 11	03MAR2020	9:54	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04NOV2014	8:07	2	Double Read
					VISIT 3A	19JAN2015	10:20	1	Double Read
					VISIT 4	04MAR2015	10:09	2	Double Read
					VISIT 6	20JUL2015	10:14	2	Double Read
					VISIT 7	14JAN2016	10:16	2	Double Read
					VISIT 8	30JAN2017	10:28	2	Double Read
					VISIT 11	03MAR2020	9:54	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	04NOV2014	8:07	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	19JAN2015	10:20	N	Double Read
					VISIT 4	04MAR2015	10:09	N	Double Read
					VISIT 6	20JUL2015	10:14	N	Double Read
					VISIT 7	14JAN2016	10:16	N	Double Read
					VISIT 8	30JAN2017	10:28	N	Double Read
					VISIT 11	03MAR2020	9:54	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04NOV2014	8:07	N	Double Read
					VISIT 3A	19JAN2015	10:20	N	Double Read
					VISIT 4	04MAR2015	10:09	N	Double Read
					VISIT 6	20JUL2015	10:14	N	Double Read
					VISIT 7	14JAN2016	10:16	N	Double Read
					VISIT 8	30JAN2017	10:28	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	03MAR2020	9:54	N	Double Read
					Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
					Baseline	04NOV2014	8:07	N	Double Read
					VISIT 3A	19JAN2015	10:20	N	Double Read
					VISIT 4	04MAR2015	10:09	N	Double Read
					VISIT 6	20JUL2015	10:14	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	14JAN2016	10:16	N	Double Read
					VISIT 8	30JAN2017	10:28	N	Double Read
					VISIT 11	03MAR2020	9:54	N	Double Read
					Baseline	04NOV2014	8:07	N	Double Read
					VISIT 3A	19JAN2015	10:20	N	Double Read
					VISIT 4	04MAR2015	10:09	N	Double Read
					VISIT 6	20JUL2015	10:14	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	14JAN2016	10:16	N	Double Read
					VISIT 8	30JAN2017	10:28	N	Double Read
					VISIT 11	03MAR2020	9:54	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	04NOV2014	8:07	N	Double Read
					VISIT 3A	19JAN2015	10:20	N	Double Read
					VISIT 4	04MAR2015	10:09	N	Double Read
					VISIT 6	20JUL2015	10:14	N	Double Read
					VISIT 7	14JAN2016	10:16	N	Double Read
					VISIT 8	30JAN2017	10:28	N	Double Read
					VISIT 11	03MAR2020	9:54	N	Double Read
Fracture	5_S		General		Baseline	04NOV2014	8:07	N	Double Read
					VISIT 3A	19JAN2015	10:20	N	Double Read
					VISIT 4	04MAR2015	10:09	N	Double Read
					VISIT 6	20JUL2015	10:14	N	Double Read
					VISIT 7	14JAN2016	10:16	N	Double Read
					VISIT 8	30JAN2017	10:28	N	Double Read
					VISIT 11	03MAR2020	9:54	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	04NOV2014	8:07	10.51	Double Read
					VISIT 3A	19JAN2015	10:20	11.485	Double Read
					VISIT 4	04MAR2015	10:09	11.815	Double Read
					VISIT 6	20JUL2015	10:14	10.155	Double Read
					VISIT 7	14JAN2016	10:16	10.485	Double Read
					VISIT 8	30JAN2017	10:28	10.92	Double Read
					VISIT 11	03MAR2020	9:54	11.245	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	04NOV2014	8:07	13.365	Double Read
					VISIT 3A	19JAN2015	10:20	13.965	Double Read
					VISIT 4	04MAR2015	10:09	13.155	Double Read
					VISIT 6	20JUL2015	10:14	13.485	Double Read
					VISIT 7	14JAN2016	10:16	13.825	Double Read
					VISIT 8	30JAN2017	10:28	13.68	Double Read
					VISIT 11	03MAR2020	9:54	13.105	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	04NOV2014	8:07	8.571675	Double Read
					VISIT 3A	19JAN2015	10:20	7.23269	Double Read
					VISIT 4	04MAR2015	10:09	7.919465	Double Read
					VISIT 6	20JUL2015	10:14	7.92442	Double Read
					VISIT 7	14JAN2016	10:16	6.93372	Double Read
					VISIT 8	30JAN2017	10:28	7.740765	Double Read
					VISIT 11	03MAR2020	9:54	8.41368	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	04NOV2014	8:07	10.71925	Double Read
					VISIT 3A	19JAN2015	10:20	9.044175	Double Read
					VISIT 4	04MAR2015	10:09	10.9956	Double Read
					VISIT 6	20JUL2015	10:14	10.7531	Double Read
					VISIT 7	14JAN2016	10:16	10.64245	Double Read
					VISIT 8	30JAN2017	10:28	11.0136	Double Read
					VISIT 11	03MAR2020	9:54	10.9329	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	04NOV2014	8:07	N	Double Read
					VISIT 3A	19JAN2015	10:20	N	Double Read
					VISIT 4	04MAR2015	10:09	N	Double Read
					VISIT 6	20JUL2015	10:14	N	Double Read
					VISIT 7	14JAN2016	10:16	N	Double Read
					VISIT 8	30JAN2017	10:28	N	Double Read
					VISIT 11	03MAR2020	9:54	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04NOV2014	8:07	N	Double Read
					VISIT 3A	19JAN2015	10:20	N	Double Read
					VISIT 4	04MAR2015	10:09	N	Double Read
					VISIT 6	20JUL2015	10:14	N	Double Read
					VISIT 7	14JAN2016	10:16	N	Double Read
					VISIT 8	30JAN2017	10:28	N	Double Read
					VISIT 11	03MAR2020	9:54	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	04NOV2014	8:07	N	Double Read
					VISIT 3A	19JAN2015	10:20	N	Double Read
					VISIT 4	04MAR2015	10:09	N	Double Read
					VISIT 6	20JUL2015	10:14	N	Double Read
					VISIT 7	14JAN2016	10:16	N	Double Read
					VISIT 8	30JAN2017	10:28	N	Double Read
					VISIT 11	03MAR2020	9:54	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04NOV2014	8:07	N	Double Read
					VISIT 3A	19JAN2015	10:20	N	Double Read
					VISIT 4	04MAR2015	10:09	N	Double Read
					VISIT 6	20JUL2015	10:14	N	Double Read
					VISIT 7	14JAN2016	10:16	N	Double Read
					VISIT 8	30JAN2017	10:28	N	Double Read
					VISIT 11	03MAR2020	9:54	N	Double Read
Normal lordotic LS	5_S		General		Baseline	04NOV2014	8:07	Y	Double Read
					VISIT 3A	19JAN2015	10:20	Y	Double Read
					VISIT 4	04MAR2015	10:09	Y	Double Read
					VISIT 6	20JUL2015	10:14	Y	Double Read
					VISIT 7	14JAN2016	10:16	Y	Double Read
					VISIT 8	30JAN2017	10:28	Y	Double Read
					VISIT 11	03MAR2020	9:54	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20	0	Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	04NOV2014	8:07	0	Double Read
					VISIT 3A	19JAN2015	10:20	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	04MAR2015	10:09	0	Double Read
					VISIT 6	20JUL2015	10:14	0	Double Read
					VISIT 7	14JAN2016	10:16	0	Double Read
					VISIT 8	30JAN2017	10:28	0	Double Read
					VISIT 11	03MAR2020	9:54	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04NOV2014	8:07	0	Double Read
					VISIT 3A	19JAN2015	10:20	0	Double Read
					VISIT 4	04MAR2015	10:09	0	Double Read
					VISIT 6	20JUL2015	10:14	0	Double Read
					VISIT 7	14JAN2016	10:16	0	Double Read
					VISIT 8	30JAN2017	10:28	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 11	03MAR2020	9:54	0	Double Read
					Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54	N	Double Read
					Baseline	04NOV2014	8:07	N	Double Read
					VISIT 3A	19JAN2015	10:20	N	Double Read
					VISIT 4	04MAR2015	10:09	N	Double Read
					VISIT 6	20JUL2015	10:14	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	14JAN2016	10:16	N	Double Read
					VISIT 8	30JAN2017	10:28	N	Double Read
					VISIT 11	03MAR2020	9:54	N	Double Read
					Baseline	04NOV2014	8:07	N	Double Read
					VISIT 3A	19JAN2015	10:20	N	Double Read
					VISIT 4	04MAR2015	10:09	N	Double Read
					VISIT 6	20JUL2015	10:14	N	Double Read
					VISIT 7	14JAN2016	10:16	N	Double Read
					VISIT 8	30JAN2017	10:28	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	30JAN2017	10:28	N	Double Read
					VISIT 11	03MAR2020	9:54	N	Double Read
Relevant scoliosis	5_S		General		Baseline	04NOV2014	8:07	N	Double Read
					VISIT 3A	19JAN2015	10:20	N	Double Read
					VISIT 4	04MAR2015	10:09	N	Double Read
					VISIT 6	20JUL2015	10:14	N	Double Read
					VISIT 7	14JAN2016	10:16	N	Double Read
					VISIT 8	30JAN2017	10:28	N	Double Read
					VISIT 11	03MAR2020	9:54	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	04NOV2014	8:07	N	Double Read
					VISIT 3A	19JAN2015	10:20	N	Double Read
					VISIT 4	04MAR2015	10:09	N	Double Read
					VISIT 6	20JUL2015	10:14	N	Double Read
					VISIT 7	14JAN2016	10:16	N	Double Read
					VISIT 8	30JAN2017	10:28	N	Double Read
					VISIT 11	03MAR2020	9:54	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04NOV2014	8:07	N	Double Read
					VISIT 3A	19JAN2015	10:20	N	Double Read
					VISIT 4	04MAR2015	10:09	N	Double Read
					VISIT 6	20JUL2015	10:14	N	Double Read
					VISIT 7	14JAN2016	10:16	N	Double Read
					VISIT 8	30JAN2017	10:28	N	Double Read
					VISIT 11	03MAR2020	9:54	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	04NOV2014	8:07	63.15824	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	19JAN2015	10:20	64.17952	Double Read
					VISIT 4	04MAR2015	10:09	57.81648	Double Read
					VISIT 6	20JUL2015	10:14	59.34624	Double Read
					VISIT 7	14JAN2016	10:16	61.11968	Double Read
					VISIT 8	30JAN2017	10:28	63.2784	Double Read
					VISIT 11	03MAR2020	9:54	83.06704	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	04NOV2014	8:07	105.23152	Double Read
					VISIT 3A	19JAN2015	10:20	102.64432	Double Read
					VISIT 4	04MAR2015	10:09	95.71808	Double Read
					VISIT 6	20JUL2015	10:14	104.2464	Double Read
					VISIT 7	14JAN2016	10:16	100.49312	Double Read
					VISIT 8	30JAN2017	10:28	100.88032	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	03MAR2020	9:54	110.41568	Double Read
					VISIT 3A	19JAN2015	10:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 8	30JAN2017	10:28		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	03MAR2020	9:54		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	04NOV2014	8:07	lower	Double Read
					VISIT 3A	19JAN2015	10:20	lower	Double Read
					VISIT 4	04MAR2015	10:09	lower	Double Read
					VISIT 6	20JUL2015	10:14	lower	Double Read
					VISIT 7	14JAN2016	10:16	lower	Double Read
					VISIT 8	30JAN2017	10:28	lower	Double Read
					VISIT 11	03MAR2020	9:54	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	04NOV2014	8:07	8.9859011381	Double Read
					VISIT 3A	19JAN2015	10:20	8.98982843554	Double Read
					VISIT 4	04MAR2015	10:09	6.50646509258	Double Read
					VISIT 6	20JUL2015	10:14	7.70058094105	Double Read
					VISIT 7	14JAN2016	10:16	8.24595889247	Double Read
					VISIT 8	30JAN2017	10:28	2.33488024461	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	VISIT 11	03MAR2020	9:54	11.127426533	Double Read
					Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	04NOV2014	8:07	4.4731374214	Double Read
					VISIT 3A	19JAN2015	10:20	1.6683268218	Double Read
					VISIT 4	04MAR2015	10:09	4.2709155766	Double Read
					VISIT 6	20JUL2015	10:14	2.7469746899	Double Read
					VISIT 7	14JAN2016	10:16	1.9817700017	Double Read
					VISIT 8	30JAN2017	10:28	2.3942993035	Double Read
					VISIT 11	03MAR2020	9:54	3.6804280618	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	04NOV2014	8:07	9622.0	Double Read
					VISIT 3A	19JAN2015	10:20	9633.0	Double Read
					VISIT 4	04MAR2015	10:09	9354.0	Double Read
					VISIT 6	20JUL2015	10:14	9282.5	Double Read
					VISIT 7	14JAN2016	10:16	8639.0	Double Read
					VISIT 8	30JAN2017	10:28	9421.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0701 Age=27 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 11	03MAR2020	9:54	8899.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	04NOV2014	8:07	11979.0	Double Read
					VISIT 3A	19JAN2015	10:20	12031.0	Double Read
					VISIT 4	04MAR2015	10:09	12162.5	Double Read
					VISIT 6	20JUL2015	10:14	12026.5	Double Read
					VISIT 7	14JAN2016	10:16	11690.0	Double Read
					VISIT 8	30JAN2017	10:28	11782.0	Double Read
					VISIT 11	03MAR2020	9:54	12184.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	04NOV2014	8:07		Double Read
					VISIT 3A	19JAN2015	10:20		Double Read
					VISIT 4	04MAR2015	10:09		Double Read
					VISIT 6	20JUL2015	10:14		Double Read
					VISIT 7	14JAN2016	10:16		Double Read
					VISIT 8	30JAN2017	10:28		Double Read
					VISIT 11	03MAR2020	9:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0702 Age=32 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	16JAN2015	8:16	3	Double Read
					VISIT 4	02MAR2015	10:32	3	Double Read
					VISIT 6	21JUL2015	12:30	3	Double Read
					VISIT 8	14FEB2018	10:00	3	Double Read
					VISIT 11	20FEB2020	10:07	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16JAN2015	8:16	2	Double Read
					VISIT 4	02MAR2015	10:32	2	Double Read
					VISIT 6	21JUL2015	12:30	2	Double Read
					VISIT 8	14FEB2018	10:00	2	Double Read
					VISIT 11	20FEB2020	10:07	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	16JAN2015	8:16	N	Double Read
					VISIT 4	02MAR2015	10:32	N	Double Read
					VISIT 6	21JUL2015	12:30	N	Double Read
					VISIT 8	14FEB2018	10:00	N	Double Read
					VISIT 11	20FEB2020	10:07	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16JAN2015	8:16	N	Double Read
					VISIT 4	02MAR2015	10:32	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0702 Age=32 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 6	21JUL2015	12:30	N	Double Read
					VISIT 8	14FEB2018	10:00	N	Double Read
					VISIT 11	20FEB2020	10:07	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	16JAN2015	8:16	Y	Double Read
					VISIT 4	02MAR2015	10:32	Y	Double Read
					VISIT 6	21JUL2015	12:30	Y	Double Read
					VISIT 8	14FEB2018	10:00	Y	Double Read
					VISIT 11	20FEB2020	10:07	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16JAN2015	8:16	N	Double Read
					VISIT 4	02MAR2015	10:32	N	Double Read
					VISIT 6	21JUL2015	12:30	N	Double Read
					VISIT 8	14FEB2018	10:00	N	Double Read
Extradiscal fluid collection	5_S		General		VISIT 11	20FEB2020	10:07	N	Double Read
					Baseline	16JAN2015	8:16	N	Double Read
					VISIT 4	02MAR2015	10:32	N	Double Read
					VISIT 6	21JUL2015	12:30	N	Double Read
					VISIT 8	14FEB2018	10:00	N	Double Read
Fracture	5_S		General		VISIT 11	20FEB2020	10:07	N	Double Read
					Baseline	16JAN2015	8:16	N	Double Read
					VISIT 4	02MAR2015	10:32	N	Double Read
					VISIT 6	21JUL2015	12:30	N	Double Read
					VISIT 8	14FEB2018	10:00	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 11	20FEB2020	10:07	N	Double Read
					Baseline	16JAN2015	8:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0702 Age=32 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16JAN2015	8:16	11.765	Double Read
					VISIT 4	02MAR2015	10:32	11.655	Double Read
					VISIT 6	21JUL2015	12:30	11.515	Double Read
					VISIT 8	14FEB2018	10:00	11.015	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 11	20FEB2020	10:07	9.73	Double Read
					Baseline	16JAN2015	8:16	14.385	Double Read
					VISIT 4	02MAR2015	10:32	13.395	Double Read
					VISIT 6	21JUL2015	12:30	13.695	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 8	14FEB2018	10:00	13.175	Double Read
					VISIT 11	20FEB2020	10:07	13.005	Double Read
					Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
					Baseline	16JAN2015	8:16	8.247655	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 4	02MAR2015	10:32	6.93796	Double Read
					VISIT 6	21JUL2015	12:30	6.68279	Double Read
					VISIT 8	14FEB2018	10:00	7.231005	Double Read
					VISIT 11	20FEB2020	10:07	6.85695	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16JAN2015	8:16	10.5258	Double Read
					VISIT 4	02MAR2015	10:32	10.0691	Double Read
					VISIT 6	21JUL2015	12:30	9.91187	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0702 Age=32 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 8	14FEB2018	10:00	9.96534	Double Read
					VISIT 11	20FEB2020	10:07	10.19973	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	16JAN2015	8:16	N	Double Read
					VISIT 4	02MAR2015	10:32	N	Double Read
					VISIT 6	21JUL2015	12:30	N	Double Read
					VISIT 8	14FEB2018	10:00	N	Double Read
					VISIT 11	20FEB2020	10:07	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16JAN2015	8:16	N	Double Read
					VISIT 4	02MAR2015	10:32	N	Double Read
					VISIT 6	21JUL2015	12:30	N	Double Read
					VISIT 8	14FEB2018	10:00	N	Double Read
					VISIT 11	20FEB2020	10:07	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	16JAN2015	8:16	N	Double Read
					VISIT 4	02MAR2015	10:32	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0702 Age=32 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		VISIT 6	21JUL2015	12:30	N	Double Read
					VISIT 8	14FEB2018	10:00	N	Double Read
					VISIT 11	20FEB2020	10:07	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16JAN2015	8:16	N	Double Read
					VISIT 4	02MAR2015	10:32	N	Double Read
					VISIT 6	21JUL2015	12:30	N	Double Read
					VISIT 8	14FEB2018	10:00	N	Double Read
					VISIT 11	20FEB2020	10:07	N	Double Read
Normal lordotic LS	5_S		General		Baseline	16JAN2015	8:16	Y	Double Read
					VISIT 4	02MAR2015	10:32	Y	Double Read
					VISIT 6	21JUL2015	12:30	Y	Double Read
					VISIT 8	14FEB2018	10:00	Y	Double Read
					VISIT 11	20FEB2020	10:07	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	16JAN2015	8:16	0	Double Read
					VISIT 4	02MAR2015	10:32	0	Double Read
					VISIT 6	21JUL2015	12:30	0	Double Read
					VISIT 8	14FEB2018	10:00	0	Double Read
					VISIT 11	20FEB2020	10:07	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16JAN2015	8:16	0	Double Read
					VISIT 4	02MAR2015	10:32	0	Double Read
					VISIT 6	21JUL2015	12:30	0	Double Read
					VISIT 8	14FEB2018	10:00	0	Double Read
					VISIT 11	20FEB2020	10:07	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0702 Age=32 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	16JAN2015	8:16	N	Double Read
					VISIT 4	02MAR2015	10:32	N	Double Read
					VISIT 6	21JUL2015	12:30	N	Double Read
					VISIT 8	14FEB2018	10:00	N	Double Read
					VISIT 11	20FEB2020	10:07	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16JAN2015	8:16	N	Double Read
					VISIT 4	02MAR2015	10:32	N	Double Read
					VISIT 6	21JUL2015	12:30	N	Double Read
					VISIT 8	14FEB2018	10:00	N	Double Read
					VISIT 11	20FEB2020	10:07	N	Double Read
Relevant scoliosis	5_S		General		Baseline	16JAN2015	8:16	N	Double Read
					VISIT 4	02MAR2015	10:32	N	Double Read
					VISIT 6	21JUL2015	12:30	N	Double Read
					VISIT 8	14FEB2018	10:00	N	Double Read
					VISIT 11	20FEB2020	10:07	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	16JAN2015	8:16	N	Double Read
					VISIT 4	02MAR2015	10:32	N	Double Read
					VISIT 6	21JUL2015	12:30	N	Double Read
					VISIT 8	14FEB2018	10:00	N	Double Read
					VISIT 11	20FEB2020	10:07	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0702 Age=32 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16JAN2015	8:16	N	Double Read
					VISIT 4	02MAR2015	10:32	N	Double Read
					VISIT 6	21JUL2015	12:30	N	Double Read
					VISIT 8	14FEB2018	10:00	N	Double Read
					VISIT 11	20FEB2020	10:07	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16JAN2015	8:16	76.45472	Double Read
					VISIT 4	02MAR2015	10:32	83.26128	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0702 Age=32 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 6	21JUL2015	12:30	71.8088	Double Read
					VISIT 8	14FEB2018	10:00	68.24	Double Read
					VISIT 11	20FEB2020	10:07	100.54064	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16JAN2015	8:16	106.02016	Double Read
					VISIT 4	02MAR2015	10:32	102.97136	Double Read
					VISIT 6	21JUL2015	12:30	101.87936	Double Read
					VISIT 8	14FEB2018	10:00	102.58192	Double Read
					VISIT 11	20FEB2020	10:07	123.74144	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0702 Age=32 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0702 Age=32 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	16JAN2015	8:16	lower	Double Read
					VISIT 4	02MAR2015	10:32	lower	Double Read
					VISIT 6	21JUL2015	12:30	lower	Double Read
					VISIT 8	14FEB2018	10:00	lower	Double Read
					VISIT 11	20FEB2020	10:07	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0702 Age=32 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	16JAN2015	8:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0702 Age=32 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16JAN2015	8:16	2.00116867674	Double Read
					VISIT 4	02MAR2015	10:32	5.43570579242	Double Read
					VISIT 6	21JUL2015	12:30	4.86058773569	Double Read
					VISIT 8	14FEB2018	10:00	9.69852896212	Double Read
					VISIT 11	20FEB2020	10:07	4.79021572958	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16JAN2015	8:16	2.5225072193	Double Read
					VISIT 4	02MAR2015	10:32	3.93522677085	Double Read
					VISIT 6	21JUL2015	12:30	4.90723288602	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0702 Age=32 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 8	14FEB2018	10:00	2.04917954816	Double Read
					VISIT 11	20FEB2020	10:07	5.88868354	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0702 Age=32 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16JAN2015	8:16	9739.5	Double Read
					VISIT 4	02MAR2015	10:32	8420.0	Double Read
					VISIT 6	21JUL2015	12:30	8220.0	Double Read
					VISIT 8	14FEB2018	10:00	7658.0	Double Read
					VISIT 11	20FEB2020	10:07	7149.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16JAN2015	8:16	13025.5	Double Read
					VISIT 4	02MAR2015	10:32	12297.5	Double Read
					VISIT 6	21JUL2015	12:30	12344.5	Double Read
					VISIT 8	14FEB2018	10:00	12741.0	Double Read
					VISIT 11	20FEB2020	10:07	12238.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	16JAN2015	8:16		Double Read
					VISIT 4	02MAR2015	10:32		Double Read
					VISIT 6	21JUL2015	12:30		Double Read
					VISIT 8	14FEB2018	10:00		Double Read
					VISIT 11	20FEB2020	10:07		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	27FEB2015	10:19	3	Double Read
					VISIT 3A	18MAY2015	12:49	4	Double Read
					VISIT 4	29JUN2015	10:10	3	Double Read
					VISIT 6	09NOV2015	10:00	3	Double Read
					VISIT 7	09MAY2016	9:57	3	Double Read
					VISIT 8	24APR2017	10:27	3	Double Read
					VISIT 11	20JUL2020	9:14	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5	3_4	Central Disc		Baseline	27FEB2015	10:19	3	Double Read
					VISIT 3A	18MAY2015	12:49	4	Double Read
					VISIT 4	29JUN2015	10:10	3	Double Read
					VISIT 6	09NOV2015	10:00	4	Double Read
					VISIT 7	09MAY2016	9:57	3	Double Read
					VISIT 8	24APR2017	10:27	3	Double Read
					VISIT 11	20JUL2020	9:14	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	27FEB2015	10:19	4	Double Read
					VISIT 3A	18MAY2015	12:49	4	Double Read
					VISIT 4	29JUN2015	10:10	3	Double Read
					VISIT 6	09NOV2015	10:00	3	Double Read
					VISIT 7	09MAY2016	9:57	4	Double Read
					VISIT 8	24APR2017	10:27	3	Double Read
					VISIT 11	20JUL2020	9:14	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	27FEB2015	10:19	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
					VISIT 7	09MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5	3_4	Central Disc		Baseline	27FEB2015	10:19	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5	3_4	Central Disc		VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
					VISIT 7	09MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	27FEB2015	10:19	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
					VISIT 7	09MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	10:27	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5	3_4	Caudal Disc		VISIT 11	20JUL2020	9:14	N	Double Read
					Baseline	27FEB2015	10:19	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
					VISIT 7	09MAY2016	9:57	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5	3_4	Central Disc		VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read
					Baseline	27FEB2015	10:19	Y	Double Read
					VISIT 3A	18MAY2015	12:49	Y	Double Read
					VISIT 4	29JUN2015	10:10	Y	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
Dorsal disc extrusion (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		VISIT 7	09MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read
					Baseline	27FEB2015	10:19	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	Y	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		VISIT 7	09MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read
Extradiscal fluid collection	4_5	3_4	General		Baseline	27FEB2015	10:19	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
					VISIT 7	09MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read
Fracture	4_5	3_4	General		Baseline	27FEB2015	10:19	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
					VISIT 7	09MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	27FEB2015	10:19	12.655	Double Read
					VISIT 3A	18MAY2015	12:49	11.335	Double Read
					VISIT 4	29JUN2015	10:10	9.255	Double Read
					VISIT 6	09NOV2015	10:00	10.085	Double Read
					VISIT 7	09MAY2016	9:57	9.445	Double Read
					VISIT 8	24APR2017	10:27	9.02	Double Read
					VISIT 11	20JUL2020	9:14	10.275	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	27FEB2015	10:19	12.065	Double Read
					VISIT 3A	18MAY2015	12:49	10.075	Double Read
					VISIT 4	29JUN2015	10:10	10.79	Double Read
					VISIT 6	09NOV2015	10:00	10.41	Double Read
					VISIT 7	09MAY2016	9:57	10.58	Double Read
					VISIT 8	24APR2017	10:27	9.89	Double Read
					VISIT 11	20JUL2020	9:14	10.83	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	27FEB2015	10:19	11.87	Double Read
					VISIT 3A	18MAY2015	12:49	10.595	Double Read
					VISIT 4	29JUN2015	10:10	11.585	Double Read
					VISIT 6	09NOV2015	10:00	11.315	Double Read
					VISIT 7	09MAY2016	9:57	11.425	Double Read
					VISIT 8	24APR2017	10:27	11.235	Double Read
					VISIT 11	20JUL2020	9:14	11.485	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	27FEB2015	10:19	7.18862	Double Read
					VISIT 3A	18MAY2015	12:49	7.201165	Double Read
					VISIT 4	29JUN2015	10:10	6.959285	Double Read
					VISIT 6	09NOV2015	10:00	7.443565	Double Read
					VISIT 7	09MAY2016	9:57	6.5018	Double Read
					VISIT 8	24APR2017	10:27	6.850685	Double Read
					VISIT 11	20JUL2020	9:14	6.431685	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	27FEB2015	10:19	8.14498	Double Read
					VISIT 3A	18MAY2015	12:49	6.71633	Double Read
					VISIT 4	29JUN2015	10:10	7.99449	Double Read
					VISIT 6	09NOV2015	10:00	7.45518	Double Read
					VISIT 7	09MAY2016	9:57	7.49376	Double Read
					VISIT 8	24APR2017	10:27	6.545425	Double Read
					VISIT 11	20JUL2020	9:14	8.04732	Double Read
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	27FEB2015	10:19	9.141795	Double Read
					VISIT 3A	18MAY2015	12:49	7.93901	Double Read
					VISIT 4	29JUN2015	10:10	8.582485	Double Read
					VISIT 6	09NOV2015	10:00	8.525645	Double Read
					VISIT 7	09MAY2016	9:57	8.14482	Double Read
					VISIT 8	24APR2017	10:27	8.03811	Double Read
					VISIT 11	20JUL2020	9:14	8.582445	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	27FEB2015	10:19	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
					VISIT 7	09MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5	3_4	Central Disc		Baseline	27FEB2015	10:19	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
					VISIT 7	09MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	27FEB2015	10:19	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
					VISIT 7	09MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	27FEB2015	10:19	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
					VISIT 7	09MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5	3_4	Central Disc		Baseline	27FEB2015	10:19	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
					VISIT 7	09MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	27FEB2015	10:19	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
					VISIT 7	09MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read
Normal lordotic LS	4_5	3_4	General		Baseline	27FEB2015	10:19	Y	Double Read
					VISIT 3A	18MAY2015	12:49	Y	Double Read
					VISIT 4	29JUN2015	10:10	Y	Double Read
					VISIT 6	09NOV2015	10:00	Y	Double Read
					VISIT 7	09MAY2016	9:57	Y	Double Read
					VISIT 8	24APR2017	10:27	Y	Double Read
					VISIT 11	20JUL2020	9:14	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	27FEB2015	10:19	0	Double Read
					VISIT 3A	18MAY2015	12:49	0	Double Read
					VISIT 4	29JUN2015	10:10	0	Double Read
					VISIT 6	09NOV2015	10:00	0	Double Read
					VISIT 7	09MAY2016	9:57	0	Double Read
					VISIT 8	24APR2017	10:27	0	Double Read
					VISIT 11	20JUL2020	9:14	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5	3_4	Central Disc		Baseline	27FEB2015	10:19	2	Double Read
					VISIT 3A	18MAY2015	12:49	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5	3_4	Central Disc		VISIT 4	29JUN2015	10:10	2	Double Read
					VISIT 6	09NOV2015	10:00	0	Double Read
					VISIT 7	09MAY2016	9:57	1	Double Read
					VISIT 8	24APR2017	10:27	1	Double Read
					VISIT 11	20JUL2020	9:14	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	27FEB2015	10:19	0	Double Read
					VISIT 3A	18MAY2015	12:49	0	Double Read
					VISIT 4	29JUN2015	10:10	0	Double Read
					VISIT 6	09NOV2015	10:00	0	Double Read
					VISIT 7	09MAY2016	9:57	0	Double Read
					VISIT 8	24APR2017	10:27	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5	3_4	Caudal Disc		VISIT 11	20JUL2020	9:14	0	Double Read
					Baseline	27FEB2015	10:19	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
					VISIT 7	09MAY2016	9:57	N	Double Read
Protruding osteophyte (Central Disc)	4_5	3_4	Central Disc		VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read
					Baseline	27FEB2015	10:19	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
Protruding osteophyte (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		VISIT 7	09MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
					VISIT 7	09MAY2016	9:57	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read
Relevant scoliosis	4_5	3_4	General		Baseline	27FEB2015	10:19	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
					VISIT 7	09MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5	3_4	Caudal Disc		Baseline	27FEB2015	10:19	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
					VISIT 7	09MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5	3_4	Central Disc		Baseline	27FEB2015	10:19	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
					VISIT 7	09MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	4_5	3_4	Cranial Disc, add. treated		Baseline	27FEB2015	10:19	N	Double Read
					VISIT 3A	18MAY2015	12:49	N	Double Read
					VISIT 4	29JUN2015	10:10	N	Double Read
					VISIT 6	09NOV2015	10:00	N	Double Read
					VISIT 7	09MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	10:27	N	Double Read
					VISIT 11	20JUL2020	9:14	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5	3_4	Caudal Disc	Anulus Fibrosus	Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	27FEB2015	10:19	81.1136	Double Read
					VISIT 3A	18MAY2015	12:49	72.4456	Double Read
					VISIT 4	29JUN2015	10:10	58.68256	Double Read
					VISIT 6	09NOV2015	10:00	67.22496	Double Read
					VISIT 7	09MAY2016	9:57	69.8744	Double Read
					VISIT 8	24APR2017	10:27	65.53856	Double Read
					VISIT 11	20JUL2020	9:14	88.82688	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5	3_4	Caudal Disc	Nucleus Pulposus	Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5	3_4	Central Disc	Anulus Fibrosus	Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	27FEB2015	10:19	87.64864	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	VISIT 3A	18MAY2015	12:49	72.27312	Double Read
					VISIT 4	29JUN2015	10:10	62.6152	Double Read
					VISIT 6	09NOV2015	10:00	65.50336	Double Read
					VISIT 7	09MAY2016	9:57	66.43664	Double Read
					VISIT 8	24APR2017	10:27	106.8152	Double Read
					VISIT 11	20JUL2020	9:14	100.41568	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5	3_4	Central Disc	Nucleus Pulposus	Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
T2 (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	3_4	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
T2 (ms) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	27FEB2015	10:19	62.20752	Double Read
					VISIT 3A	18MAY2015	12:49	66.20048	Double Read
					VISIT 4	29JUN2015	10:10	58.62992	Double Read
					VISIT 6	09NOV2015	10:00	63.88768	Double Read
					VISIT 7	09MAY2016	9:57	63.188	Double Read
					VISIT 8	24APR2017	10:27	64.27648	Double Read
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	3_4	Cranial Disc, add. treated	Nucleus Pulposus	VISIT 11	20JUL2020	9:14	84.00416	Double Read
					VISIT 3A	18MAY2015	12:49		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	3_4	Cranial Disc, add. treated	Nucleus Pulposus	VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5	3_4	Caudal Disc		Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5	3_4	Central Disc		Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	4_5	3_4	Cranial Disc, add. treated		Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5	3_4	Caudal Disc		Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5	3_4	Central Disc		Baseline	27FEB2015	10:19	equal	Double Read
					VISIT 3A	18MAY2015	12:49	equal	Double Read
					VISIT 4	29JUN2015	10:10	lower	Double Read
					VISIT 6	09NOV2015	10:00	equal	Double Read
					VISIT 7	09MAY2016	9:57	equal	Double Read
					VISIT 8	24APR2017	10:27	higher	Double Read
					VISIT 11	20JUL2020	9:14	equal	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, add. treated,)	4_5	3_4	Cranial Disc, add. treated		Baseline	27FEB2015	10:19	lower	Double Read
					VISIT 3A	18MAY2015	12:49	equal	Double Read
					VISIT 4	29JUN2015	10:10	lower	Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27	equal	Double Read
					VISIT 11	20JUL2020	9:14	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5	3_4	Caudal Disc		Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5	3_4	Caudal Disc		VISIT 11	20JUL2020	9:14		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5	3_4	Central Disc		Baseline	27FEB2015	10:19	higher	Double Read
					VISIT 3A	18MAY2015	12:49	lower	Double Read
					VISIT 4	29JUN2015	10:10	lower	Double Read
					VISIT 6	09NOV2015	10:00	lower	Double Read
					VISIT 7	09MAY2016	9:57	lower	Double Read
					VISIT 8	24APR2017	10:27	lower	Double Read
					VISIT 11	20JUL2020	9:14	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, add. treated,)	4_5	3_4	Cranial Disc, add. treated		Baseline	27FEB2015	10:19	lower	Double Read
					VISIT 3A	18MAY2015	12:49	lower	Double Read
					VISIT 4	29JUN2015	10:10	lower	Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27	lower	Double Read
					VISIT 11	20JUL2020	9:14	lower	Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5	3_4	Caudal Disc		Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5	3_4	Central Disc		Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5	3_4	Central Disc		VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, add. treated,)	4_5	3_4	Cranial Disc, add. treated		Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5	3_4	Caudal Disc	Anulus Fibrosus	Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	27FEB2015	10:19	8.0544657720	Double Read
					VISIT 3A	18MAY2015	12:49	6.1717886869	Double Read
					VISIT 4	29JUN2015	10:10	4.6429964328	Double Read
					VISIT 6	09NOV2015	10:00	5.2503957873	Double Read
					VISIT 7	09MAY2016	9:57	3.5631391201	Double Read
					VISIT 8	24APR2017	10:27	7.1748055036	Double Read
					VISIT 11	20JUL2020	9:14	6.2584406319	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5	3_4	Caudal Disc	Nucleus Pulposus	Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5	3_4	Central Disc	Anulus Fibrosus	Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	27FEB2015	10:19	7.1445761848	Double Read
					VISIT 3A	18MAY2015	12:49	2.0746798029	Double Read
					VISIT 4	29JUN2015	10:10	5.5180635298	Double Read
					VISIT 6	09NOV2015	10:00	5.0686054017	Double Read
					VISIT 7	09MAY2016	9:57	5.9792763716	Double Read
					VISIT 8	24APR2017	10:27	2.6046067606	Double Read
					VISIT 11	20JUL2020	9:14	5.4168303040	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5	3_4	Central Disc	Nucleus Pulposus	Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5	3_4	Central Disc	Nucleus Pulposus	VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	3_4	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	27FEB2015	10:19	8.8594462374	Double Read
					VISIT 3A	18MAY2015	12:49	11.644301002	Double Read
					VISIT 4	29JUN2015	10:10	9.1217937829	Double Read
					VISIT 6	09NOV2015	10:00	10.336334295	Double Read
					VISIT 7	09MAY2016	9:57	13.238185833	Double Read
					VISIT 8	24APR2017	10:27	5.9453032104	Double Read
					VISIT 11	20JUL2020	9:14	6.8965517241	Double Read
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	3_4	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5	3_4	Caudal Disc	Anulus Fibrosus	Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5	3_4	Caudal Disc	Complete Disc	Baseline	27FEB2015	10:19	11263.0	Double Read
					VISIT 3A	18MAY2015	12:49	10087.0	Double Read
					VISIT 4	29JUN2015	10:10	9550.0	Double Read
					VISIT 6	09NOV2015	10:00	9852.0	Double Read
					VISIT 7	09MAY2016	9:57	9678.5	Double Read
					VISIT 8	24APR2017	10:27	9028.5	Double Read
					VISIT 11	20JUL2020	9:14	10029.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5	3_4	Caudal Disc	Nucleus Pulposus	Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5	3_4	Central Disc	Anulus Fibrosus	Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	Baseline	27FEB2015	10:19	12702.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5	3_4	Central Disc	Complete Disc	VISIT 3A	18MAY2015	12:49	11321.5	Double Read
					VISIT 4	29JUN2015	10:10	11428.5	Double Read
					VISIT 6	09NOV2015	10:00	11007.5	Double Read
					VISIT 7	09MAY2016	9:57	11639.5	Double Read
					VISIT 8	24APR2017	10:27	10147.5	Double Read
					VISIT 11	20JUL2020	9:14	11185.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5	3_4	Central Disc	Nucleus Pulposus	Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Anulus Fibrosus)	4_5	3_4	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	27FEB2015	10:19		Double Read
					VISIT 3A	18MAY2015	12:49		Double Read
					VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Complete Disc)	4_5	3_4	Cranial Disc, add. treated	Complete Disc	Baseline	27FEB2015	10:19	12987.5	Double Read
					VISIT 3A	18MAY2015	12:49	11166.5	Double Read
					VISIT 4	29JUN2015	10:10	11943.0	Double Read
					VISIT 6	09NOV2015	10:00	11635.5	Double Read
					VISIT 7	09MAY2016	9:57	12217.0	Double Read
					VISIT 8	24APR2017	10:27	11606.5	Double Read
Volume (mm^3) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	3_4	Cranial Disc, add. treated	Nucleus Pulposus	VISIT 11	20JUL2020	9:14	12534.0	Double Read
					VISIT 3A	18MAY2015	12:49		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0703 Age=35 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, add. treated, Nucleus Pulposus)	4_5	3_4	Cranial Disc, add. treated	Nucleus Pulposus	VISIT 4	29JUN2015	10:10		Double Read
					VISIT 6	09NOV2015	10:00		Double Read
					VISIT 7	09MAY2016	9:57		Double Read
					VISIT 8	24APR2017	10:27		Double Read
					VISIT 11	20JUL2020	9:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	14JUL2015	10:10	2	Double Read
					VISIT 3A	06OCT2015	10:15	3	Double Read
					VISIT 4	16NOV2015	10:00	2	Double Read
					VISIT 6	11APR2016	10:13	3	Double Read
					VISIT 7	21NOV2016	10:09	2	Double Read
					VISIT 8	02OCT2017	10:17	2	Double Read
					VISIT 11	21SEP2020	10:29	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	14JUL2015	10:10	3	Double Read
					VISIT 3A	06OCT2015	10:15	4	Double Read
					VISIT 4	16NOV2015	10:00	3	Double Read
					VISIT 6	11APR2016	10:13	3	Double Read
					VISIT 7	21NOV2016	10:09	3	Double Read
					VISIT 8	02OCT2017	10:17	3	Double Read
					VISIT 11	21SEP2020	10:29	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	10:10	3	Double Read
					VISIT 3A	06OCT2015	10:15	4	Double Read
					VISIT 4	16NOV2015	10:00	3	Double Read
					VISIT 6	11APR2016	10:13	3	Double Read
					VISIT 7	21NOV2016	10:09	3	Double Read
					VISIT 8	02OCT2017	10:17	3	Double Read
					VISIT 11	21SEP2020	10:29	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
					VISIT 7	21NOV2016	10:09	N	Double Read
					VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	14JUL2015	10:10	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
					VISIT 7	21NOV2016	10:09	N	Double Read
					VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
					VISIT 7	21NOV2016	10:09	N	Double Read
					VISIT 8	02OCT2017	10:17	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 11	21SEP2020	10:29	N	Double Read
					Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
					VISIT 7	21NOV2016	10:09	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read
					Baseline	14JUL2015	10:10	Y	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	Y	Double Read
					VISIT 6	11APR2016	10:13	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	21NOV2016	10:09	Y	Double Read
					VISIT 8	02OCT2017	10:17	Y	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read
					Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	21NOV2016	10:09	N	Double Read
					VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
					VISIT 7	21NOV2016	10:09	N	Double Read
					VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read
Fracture	4_5		General		Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
					VISIT 7	21NOV2016	10:09	N	Double Read
					VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	14JUL2015	10:10	12.015	Double Read
					VISIT 3A	06OCT2015	10:15	13.915	Double Read
					VISIT 4	16NOV2015	10:00	14.385	Double Read
					VISIT 6	11APR2016	10:13	12.645	Double Read
					VISIT 7	21NOV2016	10:09	12.635	Double Read
					VISIT 8	02OCT2017	10:17	13.44	Double Read
					VISIT 11	21SEP2020	10:29	12.84	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	14JUL2015	10:10	14.525	Double Read
					VISIT 3A	06OCT2015	10:15	14.13	Double Read
					VISIT 4	16NOV2015	10:00	15.945	Double Read
					VISIT 6	11APR2016	10:13	14.25	Double Read
					VISIT 7	21NOV2016	10:09	14.895	Double Read
					VISIT 8	02OCT2017	10:17	14.905	Double Read
					VISIT 11	21SEP2020	10:29	14.67	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	10:10	14.395	Double Read
					VISIT 3A	06OCT2015	10:15	13.315	Double Read
					VISIT 4	16NOV2015	10:00	13.85	Double Read
					VISIT 6	11APR2016	10:13	13.085	Double Read
					VISIT 7	21NOV2016	10:09	14.59	Double Read
					VISIT 8	02OCT2017	10:17	13.7	Double Read
					VISIT 11	21SEP2020	10:29	13.59	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	14JUL2015	10:10	10.296505	Double Read
					VISIT 3A	06OCT2015	10:15	10.714	Double Read
					VISIT 4	16NOV2015	10:00	10.089865	Double Read
					VISIT 6	11APR2016	10:13	10.503235	Double Read
					VISIT 7	21NOV2016	10:09	10.67085	Double Read
					VISIT 8	02OCT2017	10:17	10.7545	Double Read
					VISIT 11	21SEP2020	10:29	10.79095	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	14JUL2015	10:10	11.57355	Double Read
					VISIT 3A	06OCT2015	10:15	10.40795	Double Read
					VISIT 4	16NOV2015	10:00	11.90745	Double Read
					VISIT 6	11APR2016	10:13	10.44594	Double Read
					VISIT 7	21NOV2016	10:09	10.67645	Double Read
					VISIT 8	02OCT2017	10:17	11.36465	Double Read
					VISIT 11	21SEP2020	10:29	11.6474	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	10:10	10.315685	Double Read
					VISIT 3A	06OCT2015	10:15	9.73941	Double Read
					VISIT 4	16NOV2015	10:00	11.32905	Double Read
					VISIT 6	11APR2016	10:13	9.766125	Double Read
					VISIT 7	21NOV2016	10:09	9.248515	Double Read
					VISIT 8	02OCT2017	10:17	11.05445	Double Read
					VISIT 11	21SEP2020	10:29	11.64275	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
					VISIT 7	21NOV2016	10:09	N	Double Read
					VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
					VISIT 7	21NOV2016	10:09	N	Double Read
					VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
					VISIT 7	21NOV2016	10:09	N	Double Read
					VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
					VISIT 7	21NOV2016	10:09	N	Double Read
					VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
					VISIT 7	21NOV2016	10:09	N	Double Read
					VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
					VISIT 7	21NOV2016	10:09	N	Double Read
					VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read
Normal lordotic LS	4_5		General		Baseline	14JUL2015	10:10	Y	Double Read
					VISIT 3A	06OCT2015	10:15	Y	Double Read
					VISIT 4	16NOV2015	10:00	Y	Double Read
					VISIT 6	11APR2016	10:13	Y	Double Read
					VISIT 7	21NOV2016	10:09	Y	Double Read
					VISIT 8	02OCT2017	10:17	Y	Double Read
					VISIT 11	21SEP2020	10:29	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	14JUL2015	10:10	0	Double Read
					VISIT 3A	06OCT2015	10:15	0	Double Read
					VISIT 4	16NOV2015	10:00	0	Double Read
					VISIT 6	11APR2016	10:13	0	Double Read
					VISIT 7	21NOV2016	10:09	0	Double Read
					VISIT 8	02OCT2017	10:17	0	Double Read
					VISIT 11	21SEP2020	10:29	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	14JUL2015	10:10	0	Double Read
					VISIT 3A	06OCT2015	10:15	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 4	16NOV2015	10:00	0	Double Read
					VISIT 6	11APR2016	10:13	0	Double Read
					VISIT 7	21NOV2016	10:09	0	Double Read
					VISIT 8	02OCT2017	10:17	0	Double Read
					VISIT 11	21SEP2020	10:29	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	10:10	0	Double Read
					VISIT 3A	06OCT2015	10:15	0	Double Read
					VISIT 4	16NOV2015	10:00	0	Double Read
					VISIT 6	11APR2016	10:13	0	Double Read
					VISIT 7	21NOV2016	10:09	0	Double Read
					VISIT 8	02OCT2017	10:17	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 11	21SEP2020	10:29	0	Double Read
					Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
					VISIT 7	21NOV2016	10:09	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read
					Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	21NOV2016	10:09	N	Double Read
					VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read
					Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
					VISIT 7	21NOV2016	10:09	N	Double Read
					VISIT 8	02OCT2017	10:17	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read
Relevant scoliosis	4_5		General		Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
					VISIT 7	21NOV2016	10:09	N	Double Read
					VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
					VISIT 7	21NOV2016	10:09	N	Double Read
					VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
					VISIT 7	21NOV2016	10:09	N	Double Read
					VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	10:10	N	Double Read
					VISIT 3A	06OCT2015	10:15	N	Double Read
					VISIT 4	16NOV2015	10:00	N	Double Read
					VISIT 6	11APR2016	10:13	N	Double Read
					VISIT 7	21NOV2016	10:09	N	Double Read
					VISIT 8	02OCT2017	10:17	N	Double Read
					VISIT 11	21SEP2020	10:29	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	14JUL2015	10:10	73.64848	Double Read
					VISIT 3A	06OCT2015	10:15	77.57552	Double Read
					VISIT 4	16NOV2015	10:00	75.46048	Double Read
					VISIT 6	11APR2016	10:13	71.64192	Double Read
					VISIT 7	21NOV2016	10:09	76.5064	Double Read
					VISIT 8	02OCT2017	10:17	72.50352	Double Read
					VISIT 11	21SEP2020	10:29	96.6696	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	14JUL2015	10:10	60.42336	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	06OCT2015	10:15	64.91728	Double Read
					VISIT 4	16NOV2015	10:00	60.34112	Double Read
					VISIT 6	11APR2016	10:13	58.89536	Double Read
					VISIT 7	21NOV2016	10:09	55.65792	Double Read
					VISIT 8	02OCT2017	10:17	60.23472	Double Read
					VISIT 11	21SEP2020	10:29	75.72144	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	10:10	64.98944	Double Read
					VISIT 3A	06OCT2015	10:15	67.11056	Double Read
					VISIT 4	16NOV2015	10:00	70.36832	Double Read
					VISIT 6	11APR2016	10:13	65.26048	Double Read
					VISIT 7	21NOV2016	10:09	61.69456	Double Read
					VISIT 8	02OCT2017	10:17	62.87632	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	21SEP2020	10:29	87.73568	Double Read
					VISIT 3A	06OCT2015	10:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	14JUL2015	10:10	lower	Double Read
					VISIT 3A	06OCT2015	10:15	lower	Double Read
					VISIT 4	16NOV2015	10:00	lower	Double Read
					VISIT 6	11APR2016	10:13	equal	Double Read
					VISIT 7	21NOV2016	10:09	lower	Double Read
					VISIT 8	02OCT2017	10:17	lower	Double Read
					VISIT 11	21SEP2020	10:29	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		VISIT 11	21SEP2020	10:29		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	14JUL2015	10:10	equal	Double Read
					VISIT 3A	06OCT2015	10:15	equal	Double Read
					VISIT 4	16NOV2015	10:00	equal	Double Read
					VISIT 6	11APR2016	10:13	higher	Double Read
					VISIT 7	21NOV2016	10:09	equal	Double Read
					VISIT 8	02OCT2017	10:17	equal	Double Read
					VISIT 11	21SEP2020	10:29	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	14JUL2015	10:10	4.5378427042	Double Read
					VISIT 3A	06OCT2015	10:15	6 2.4254187192	Double Read
					VISIT 4	16NOV2015	10:00	2 14.050327841	Double Read
					VISIT 6	11APR2016	10:13	1 13.262714455	Double Read
					VISIT 7	21NOV2016	10:09	6 5.3005877356	Double Read
					VISIT 8	02OCT2017	10:17	9 7.0513198573	Double Read
					VISIT 11	21SEP2020	10:29	1 13.912029896	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	14JUL2015	10:10	8.5580023781	Double Read
					VISIT 3A	06OCT2015	10:15	7.1405401732	Double Read
					VISIT 4	16NOV2015	10:00	9.5124851367	Double Read
					VISIT 6	11APR2016	10:13	13.295858671	Double Read
					VISIT 7	21NOV2016	10:09	6.1038423645	Double Read
					VISIT 8	02OCT2017	10:17	11.490456939	Double Read
					VISIT 11	21SEP2020	10:29	11.529770681	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	10:10	6.1201426872	Double Read
					VISIT 3A	06OCT2015	10:15	2.3585187701	Double Read
					VISIT 4	16NOV2015	10:00	6.4549006285	Double Read
					VISIT 6	11APR2016	10:13	7.7830881603	Double Read
					VISIT 7	21NOV2016	10:09	3.6564022422	Double Read
					VISIT 8	02OCT2017	10:17	15.316256157	Double Read
					VISIT 11	21SEP2020	10:29	7.9700084933	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	14JUL2015	10:10		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	14JUL2015	10:10	12102.5	Double Read
					VISIT 3A	06OCT2015	10:15	13517.0	Double Read
					VISIT 4	16NOV2015	10:00	13466.0	Double Read
					VISIT 6	11APR2016	10:13	13092.0	Double Read
					VISIT 7	21NOV2016	10:09	12423.5	Double Read
					VISIT 8	02OCT2017	10:17	12016.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	14JUL2015	10:10	14312.0	Double Read
					VISIT 3A	06OCT2015	10:15	15355.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 4	16NOV2015	10:00	15833.5	Double Read
					VISIT 6	11APR2016	10:13	14024.0	Double Read
					VISIT 7	21NOV2016	10:09	14688.5	Double Read
					VISIT 8	02OCT2017	10:17	14238.5	Double Read
					VISIT 11	21SEP2020	10:29	15344.0	Double Read
Volume (mm ³) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
Volume (mm ³) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read
					VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
Volume (mm ³) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	14JUL2015	10:10	15560.5	Double Read
					VISIT 3A	06OCT2015	10:15	15249.0	Double Read
					VISIT 4	16NOV2015	10:00	17080.5	Double Read
					VISIT 6	11APR2016	10:13	15714.5	Double Read
					VISIT 7	21NOV2016	10:09	15892.5	Double Read
					VISIT 8	02OCT2017	10:17	17379.0	Double Read
Volume (mm ³) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	14JUL2015	10:10		Double Read
					VISIT 3A	06OCT2015	10:15		Double Read
					VISIT 4	16NOV2015	10:00		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0704 Age=52 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 6	11APR2016	10:13		Double Read
					VISIT 7	21NOV2016	10:09		Double Read
					VISIT 8	02OCT2017	10:17		Double Read
					VISIT 11	21SEP2020	10:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0705 Age=35 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	11AUG2015	9:57		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	11AUG2015	9:57	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11AUG2015	9:57	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	11AUG2015	9:57		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	11AUG2015	9:57	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11AUG2015	9:57	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	11AUG2015	9:57		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	11AUG2015	9:57	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11AUG2015	9:57	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	11AUG2015	9:57	N	Double Read
Fracture	5_S		General		Baseline	11AUG2015	9:57	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11AUG2015	9:57		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11AUG2015	9:57	11.97	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11AUG2015	9:57	14.475	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0705 Age=35 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11AUG2015	9:57		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11AUG2015	9:57	8.373265	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11AUG2015	9:57	11.8488	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	11AUG2015	9:57		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	11AUG2015	9:57	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11AUG2015	9:57	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	11AUG2015	9:57		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	11AUG2015	9:57	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11AUG2015	9:57	N	Double Read
Normal lordotic LS	5_S		General		Baseline	11AUG2015	9:57	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	11AUG2015	9:57		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	11AUG2015	9:57	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0705 Age=35 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11AUG2015	9:57	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	11AUG2015	9:57		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	11AUG2015	9:57	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11AUG2015	9:57	N	Double Read
Relevant scoliosis	5_S		General		Baseline	11AUG2015	9:57	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	11AUG2015	9:57		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	11AUG2015	9:57	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11AUG2015	9:57	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	11AUG2015	9:57		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11AUG2015	9:57		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	11AUG2015	9:57		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	11AUG2015	9:57		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11AUG2015	9:57	69.93072	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	11AUG2015	9:57		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0705 Age=35 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11AUG2015	9:57		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11AUG2015	9:57	84.00368	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	11AUG2015	9:57		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	11AUG2015	9:57		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	11AUG2015	9:57		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11AUG2015	9:57		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	11AUG2015	9:57		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	11AUG2015	9:57		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11AUG2015	9:57		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	11AUG2015	9:57		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0705 Age=35 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	11AUG2015	9:57	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11AUG2015	9:57		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	11AUG2015	9:57		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	11AUG2015	9:57		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11AUG2015	9:57		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	11AUG2015	9:57		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11AUG2015	9:57		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	11AUG2015	9:57		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	11AUG2015	9:57		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11AUG2015	9:57	2.23198233396	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	11AUG2015	9:57		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11AUG2015	9:57		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0705 Age=35 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11AUG2015	9:57	6.04722269407	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	11AUG2015	9:57		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	11AUG2015	9:57		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11AUG2015	9:57		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	11AUG2015	9:57		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	11AUG2015	9:57		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11AUG2015	9:57	10926.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	11AUG2015	9:57		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11AUG2015	9:57		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11AUG2015	9:57	16838.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	11AUG2015	9:57		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0706 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	3_4		Caudal Disc		Baseline	30NOV2015	10:05	3	Double Read
					VISIT 4	12JAN2016	9:46	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	3_4		Central Disc		Baseline	30NOV2015	10:05	3	Double Read
					VISIT 4	12JAN2016	9:46	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	30NOV2015	10:05	3	Double Read
					VISIT 4	12JAN2016	9:46	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	3_4		Caudal Disc		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	3_4		Central Disc		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read
Dorsal disc extrusion (Caudal Disc)	3_4		Caudal Disc		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read
Dorsal disc extrusion (Central Disc)	3_4		Central Disc		Baseline	30NOV2015	10:05	Y	Double Read
					VISIT 4	12JAN2016	9:46	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read
Extradiscal fluid collection	3_4		General		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read
Fracture	3_4		General		Baseline	30NOV2015	10:05	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0706 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Fracture	3_4		General		VISIT 4	12JAN2016	9:46	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	30NOV2015	10:05	14.975	Double Read
					VISIT 4	12JAN2016	9:46	15.49	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	30NOV2015	10:05	11.04	Double Read
					VISIT 4	12JAN2016	9:46	13.56	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	30NOV2015	10:05	11.1	Double Read
					VISIT 4	12JAN2016	9:46	11.69	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	30NOV2015	10:05	11.12045	Double Read
					VISIT 4	12JAN2016	9:46	10.61112	Double Read
Height manual (mm) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	30NOV2015	10:05	9.42324	Double Read
					VISIT 4	12JAN2016	9:46	9.95817	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	30NOV2015	10:05	8.44278	Double Read
					VISIT 4	12JAN2016	9:46	8.34259	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	3_4		Caudal Disc		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	3_4		Central Disc		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0706 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	3_4		Caudal Disc		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	3_4		Central Disc		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read
Normal lordotic LS	3_4		General		Baseline	30NOV2015	10:05	Y	Double Read
					VISIT 4	12JAN2016	9:46	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	3_4		Caudal Disc		Baseline	30NOV2015	10:05	0	Double Read
					VISIT 4	12JAN2016	9:46	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	3_4		Central Disc		Baseline	30NOV2015	10:05	0	Double Read
					VISIT 4	12JAN2016	9:46	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	30NOV2015	10:05	0	Double Read
					VISIT 4	12JAN2016	9:46	2	Double Read
Protruding osteophyte (Caudal Disc)	3_4		Caudal Disc		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read
Protruding osteophyte (Central Disc)	3_4		Central Disc		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0706 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read
Relevant scoliosis	3_4		General		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	3_4		Caudal Disc		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	3_4		Central Disc		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	30NOV2015	10:05	N	Double Read
					VISIT 4	12JAN2016	9:46	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	30NOV2015	10:05	67.6832	Double Read
					VISIT 4	12JAN2016	9:46	77.73936	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2 (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	30NOV2015	10:05	66.22384	Double Read
					VISIT 4	12JAN2016	9:46	80.45648	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0706 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	30NOV2015	10:05	65.85008	Double Read
					VISIT 4	12JAN2016	9:46	75.99696	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	3_4		Caudal Disc		Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	3_4		Central Disc		Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	3_4		Caudal Disc		Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0706 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	3_4		Central Disc		Baseline	30NOV2015	10:05	lower	Double Read
					VISIT 4	12JAN2016	9:46	equal	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	3_4		Caudal Disc		Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	3_4		Central Disc		Baseline	30NOV2015	10:05	equal	Double Read
					VISIT 4	12JAN2016	9:46	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	3_4		Caudal Disc		Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	3_4		Central Disc		Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0706 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	30NOV2015	10:05	24.8812638016	Double Read
					VISIT 4	12JAN2016	9:46	6.3249125191	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2_error (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	30NOV2015	10:05	9.80368269066	Double Read
					VISIT 4	12JAN2016	9:46	11.7924647528	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	30NOV2015	10:05	5.02991676575	Double Read
					VISIT 4	12JAN2016	9:46	4.29194496348	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0706 Age=37 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	30NOV2015	10:05	16278.5	Double Read
					VISIT 4	12JAN2016	9:46	16109.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	30NOV2015	10:05	13222.5	Double Read
					VISIT 4	12JAN2016	9:46	15868.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	30NOV2015	10:05	13195.5	Double Read
					VISIT 4	12JAN2016	9:46	14358.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	30NOV2015	10:05		Double Read
					VISIT 4	12JAN2016	9:46		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0707 Age=26 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	18FEB2016	10:29		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	18FEB2016	10:29	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18FEB2016	10:29	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	18FEB2016	10:29		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	18FEB2016	10:29	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18FEB2016	10:29	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	18FEB2016	10:29		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	18FEB2016	10:29	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18FEB2016	10:29	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	18FEB2016	10:29	N	Double Read
Fracture	5_S		General		Baseline	18FEB2016	10:29	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18FEB2016	10:29		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18FEB2016	10:29	13.06	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18FEB2016	10:29	13.345	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0707 Age=26 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18FEB2016	10:29		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18FEB2016	10:29	7.439735	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18FEB2016	10:29	11.47885	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	18FEB2016	10:29		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	18FEB2016	10:29	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18FEB2016	10:29	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	18FEB2016	10:29		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	18FEB2016	10:29	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18FEB2016	10:29	N	Double Read
Normal lordotic LS	5_S		General		Baseline	18FEB2016	10:29	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	18FEB2016	10:29		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	18FEB2016	10:29	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0707 Age=26 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18FEB2016	10:29	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	18FEB2016	10:29		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	18FEB2016	10:29	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18FEB2016	10:29	N	Double Read
Relevant scoliosis	5_S		General		Baseline	18FEB2016	10:29	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	18FEB2016	10:29		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	18FEB2016	10:29	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	18FEB2016	10:29	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	18FEB2016	10:29		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18FEB2016	10:29		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	18FEB2016	10:29		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	18FEB2016	10:29		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18FEB2016	10:29	82.06832	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	18FEB2016	10:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0707 Age=26 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	18FEB2016	10:29		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18FEB2016	10:29	96.39184	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	18FEB2016	10:29		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	18FEB2016	10:29		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	18FEB2016	10:29		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	18FEB2016	10:29		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	18FEB2016	10:29		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	18FEB2016	10:29		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	18FEB2016	10:29		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	18FEB2016	10:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0707 Age=26 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	18FEB2016	10:29	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	18FEB2016	10:29		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	18FEB2016	10:29		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	18FEB2016	10:29		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	18FEB2016	10:29		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	18FEB2016	10:29		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18FEB2016	10:29		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	18FEB2016	10:29		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	18FEB2016	10:29		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18FEB2016	10:29	7.1437948021 1	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	18FEB2016	10:29		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	18FEB2016	10:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=07/0707 Age=26 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18FEB2016	10:29	2.3856701206	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	18FEB2016	10:29		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	18FEB2016	10:29		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	18FEB2016	10:29		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	18FEB2016	10:29		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	18FEB2016	10:29		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	18FEB2016	10:29	9192.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	18FEB2016	10:29		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	18FEB2016	10:29		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	18FEB2016	10:29	12576.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	18FEB2016	10:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0801 Age=51 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	03NOV2014	7:22	3	Double Read
					VISIT 4	07JAN2015	7:08	3	Double Read
					VISIT 6	04MAY2015	7:32	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	03NOV2014	7:22	3	Double Read
					VISIT 4	07JAN2015	7:08	3	Double Read
					VISIT 6	04MAY2015	7:32	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	03NOV2014	7:22	2	Double Read
					VISIT 4	07JAN2015	7:08	2	Double Read
					VISIT 6	04MAY2015	7:32	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	03NOV2014	7:22	Y	Double Read
					VISIT 4	07JAN2015	7:08	Y	Double Read
					VISIT 6	04MAY2015	7:32	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0801 Age=51 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
Fracture	4_5		General		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	03NOV2014	7:22	12.605	Double Read
					VISIT 4	07JAN2015	7:08	14.505	Double Read
					VISIT 6	04MAY2015	7:32	13.375	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	03NOV2014	7:22	15.03	Double Read
					VISIT 4	07JAN2015	7:08	14.86	Double Read
					VISIT 6	04MAY2015	7:32	15.865	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	03NOV2014	7:22	14.645	Double Read
					VISIT 4	07JAN2015	7:08	15.34	Double Read
					VISIT 6	04MAY2015	7:32	17.0	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	03NOV2014	7:22	10.49125	Double Read
					VISIT 4	07JAN2015	7:08	10.8186	Double Read
					VISIT 6	04MAY2015	7:32	10.66615	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	03NOV2014	7:22	9.343205	Double Read
					VISIT 4	07JAN2015	7:08	10.67835	Double Read
					VISIT 6	04MAY2015	7:32	9.61302	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0801 Age=51 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	03NOV2014	7:22	13.5157	Double Read
					VISIT 4	07JAN2015	7:08	13.80565	Double Read
					VISIT 6	04MAY2015	7:32	14.2479	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0801 Age=51 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	4_5		General		Baseline	03NOV2014	7:22	Y	Double Read
					VISIT 4	07JAN2015	7:08	Y	Double Read
					VISIT 6	04MAY2015	7:32	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	03NOV2014	7:22	0	Double Read
					VISIT 4	07JAN2015	7:08	0	Double Read
					VISIT 6	04MAY2015	7:32	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	03NOV2014	7:22	0	Double Read
					VISIT 4	07JAN2015	7:08	1	Double Read
					VISIT 6	04MAY2015	7:32	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	03NOV2014	7:22	0	Double Read
					VISIT 4	07JAN2015	7:08	0	Double Read
					VISIT 6	04MAY2015	7:32	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
Relevant scoliosis	4_5		General		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	03NOV2014	7:22	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0801 Age=51 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	03NOV2014	7:22	N	Double Read
					VISIT 4	07JAN2015	7:08	N	Double Read
					VISIT 6	04MAY2015	7:32	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	03NOV2014	7:22	79.93552	Double Read
					VISIT 4	07JAN2015	7:08	82.10272	Double Read
					VISIT 6	04MAY2015	7:32	80.03184	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	03NOV2014	7:22	85.94704	Double Read
					VISIT 4	07JAN2015	7:08	85.25648	Double Read
					VISIT 6	04MAY2015	7:32	97.34752	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0801 Age=51 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	03NOV2014	7:22	93.23824	Double Read
					VISIT 4	07JAN2015	7:08	93.8768	Double Read
					VISIT 6	04MAY2015	7:32	100.20576	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0801 Age=51 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	03NOV2014	7:22	equal	Double Read
					VISIT 4	07JAN2015	7:08	higher	Double Read
					VISIT 6	04MAY2015	7:32	higher	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	03NOV2014	7:22	lower	Double Read
					VISIT 4	07JAN2015	7:08	lower	Double Read
					VISIT 6	04MAY2015	7:32	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	03NOV2014	7:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0801 Age=51 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	03NOV2014	7:22	8.4318192627	Double Read
					VISIT 4	07JAN2015	7:08	5.5381688466	Double Read
					VISIT 6	04MAY2015	7:32	7.1721080346	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0801 Age=51 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	03NOV2014	7:22	12.50697469	Double Read
					VISIT 4	07JAN2015	7:08	9.4597723798	Double Read
					VISIT 6	04MAY2015	7:32	4.3485646339	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	03NOV2014	7:22	23.150263292	Double Read
					VISIT 4	07JAN2015	7:08	4.7562425683	Double Read
					VISIT 6	04MAY2015	7:32	16.122914897	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	03NOV2014	7:22	10945.5	Double Read
					VISIT 4	07JAN2015	7:08	12133.0	Double Read
					VISIT 6	04MAY2015	7:32	10973.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0801 Age=51 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	03NOV2014	7:22	14985.0	Double Read
					VISIT 4	07JAN2015	7:08	15706.5	Double Read
					VISIT 6	04MAY2015	7:32	16181.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	03NOV2014	7:22	16580.0	Double Read
					VISIT 4	07JAN2015	7:08	18018.5	Double Read
					VISIT 6	04MAY2015	7:32	18292.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	03NOV2014	7:22		Double Read
					VISIT 4	07JAN2015	7:08		Double Read
					VISIT 6	04MAY2015	7:32		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	3_4		Caudal Disc		Baseline	27NOV2014	7:42	3	Double Read
					VISIT 3A	03MAR2015	7:12	3	Double Read
					VISIT 4	08APR2015	7:16	2	Double Read
					VISIT 6	17AUG2015	7:22	3	Double Read
					VISIT 7	22FEB2016	7:16	3	Double Read
					VISIT 8	02FEB2017	7:24	3	Double Read
					VISIT 11	19MAR2020	8:20	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	3_4		Central Disc		Baseline	27NOV2014	7:42	3	Double Read
					VISIT 3A	03MAR2015	7:12	3	Double Read
					VISIT 4	08APR2015	7:16	2	Double Read
					VISIT 6	17AUG2015	7:22	3	Double Read
					VISIT 7	22FEB2016	7:16	3	Double Read
					VISIT 8	02FEB2017	7:24	3	Double Read
					VISIT 11	19MAR2020	8:20	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	27NOV2014	7:42	2	Double Read
					VISIT 3A	03MAR2015	7:12	2	Double Read
					VISIT 4	08APR2015	7:16	2	Double Read
					VISIT 6	17AUG2015	7:22	2	Double Read
					VISIT 7	22FEB2016	7:16	2	Double Read
					VISIT 8	02FEB2017	7:24	2	Double Read
					VISIT 11	19MAR2020	8:20	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	3_4		Caudal Disc		Baseline	27NOV2014	7:42	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
					VISIT 7	22FEB2016	7:16	N	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	3_4		Central Disc		Baseline	27NOV2014	7:42	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	3_4		Central Disc		VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
					VISIT 7	22FEB2016	7:16	N	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	27NOV2014	7:42	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
					VISIT 7	22FEB2016	7:16	N	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read
Dorsal disc extrusion (Caudal Disc)	3_4		Caudal Disc		VISIT 11	19MAR2020	8:20	N	Double Read
					Baseline	27NOV2014	7:42	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
					VISIT 7	22FEB2016	7:16	N	Double Read
Dorsal disc extrusion (Central Disc)	3_4		Central Disc		VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read
					Baseline	27NOV2014	7:42	Y	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		VISIT 7	22FEB2016	7:16	Y	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read
					Baseline	27NOV2014	7:42	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		VISIT 7	22FEB2016	7:16	N	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read
Extradiscal fluid collection	3_4		General		Baseline	27NOV2014	7:42	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
					VISIT 7	22FEB2016	7:16	N	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read
Fracture	3_4		General		Baseline	27NOV2014	7:42	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
					VISIT 7	22FEB2016	7:16	N	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	27NOV2014	7:42	12.725	Double Read
					VISIT 3A	03MAR2015	7:12	13.585	Double Read
					VISIT 4	08APR2015	7:16	14.825	Double Read
					VISIT 6	17AUG2015	7:22	12.72	Double Read
					VISIT 7	22FEB2016	7:16	13.52	Double Read
					VISIT 8	02FEB2017	7:24	14.115	Double Read
					VISIT 11	19MAR2020	8:20	13.995	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	27NOV2014	7:42	11.76	Double Read
					VISIT 3A	03MAR2015	7:12	13.025	Double Read
					VISIT 4	08APR2015	7:16	14.035	Double Read
					VISIT 6	17AUG2015	7:22	12.665	Double Read
					VISIT 7	22FEB2016	7:16	12.17	Double Read
					VISIT 8	02FEB2017	7:24	12.345	Double Read
					VISIT 11	19MAR2020	8:20	11.05	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	27NOV2014	7:42	12.64	Double Read
					VISIT 3A	03MAR2015	7:12	13.395	Double Read
					VISIT 4	08APR2015	7:16	13.57	Double Read
					VISIT 6	17AUG2015	7:22	13.335	Double Read
					VISIT 7	22FEB2016	7:16	13.48	Double Read
					VISIT 8	02FEB2017	7:24	13.505	Double Read
					VISIT 11	19MAR2020	8:20	12.835	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	27NOV2014	7:42	9.069925	Double Read
					VISIT 3A	03MAR2015	7:12	9.27824	Double Read
					VISIT 4	08APR2015	7:16	8.74998	Double Read
					VISIT 6	17AUG2015	7:22	8.568755	Double Read
					VISIT 7	22FEB2016	7:16	7.688395	Double Read
					VISIT 8	02FEB2017	7:24	8.709415	Double Read
					VISIT 11	19MAR2020	8:20	9.426785	Double Read
Height manual (mm) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	27NOV2014	7:42	9.40476	Double Read
					VISIT 3A	03MAR2015	7:12	9.928995	Double Read
					VISIT 4	08APR2015	7:16	9.93342	Double Read
					VISIT 6	17AUG2015	7:22	9.788685	Double Read
					VISIT 7	22FEB2016	7:16	8.72941	Double Read
					VISIT 8	02FEB2017	7:24	8.565845	Double Read
					VISIT 11	19MAR2020	8:20	8.54944	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	27NOV2014	7:42	10.7242	Double Read
					VISIT 3A	03MAR2015	7:12	10.65935	Double Read
					VISIT 4	08APR2015	7:16	10.1954	Double Read
					VISIT 6	17AUG2015	7:22	10.98995	Double Read
					VISIT 7	22FEB2016	7:16	9.73422	Double Read
					VISIT 8	02FEB2017	7:24	10.309555	Double Read
					VISIT 11	19MAR2020	8:20	11.30215	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	3_4		Caudal Disc		Baseline	27NOV2014	7:42	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
					VISIT 7	22FEB2016	7:16	N	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	3_4		Central Disc		Baseline	27NOV2014	7:42	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
					VISIT 7	22FEB2016	7:16	N	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	27NOV2014	7:42	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
					VISIT 7	22FEB2016	7:16	N	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	3_4		Caudal Disc		Baseline	27NOV2014	7:42	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
					VISIT 7	22FEB2016	7:16	N	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	3_4		Central Disc		Baseline	27NOV2014	7:42	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
					VISIT 7	22FEB2016	7:16	N	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	27NOV2014	7:42	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
					VISIT 7	22FEB2016	7:16	N	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read
Normal lordotic LS	3_4		General		Baseline	27NOV2014	7:42	Y	Double Read
					VISIT 3A	03MAR2015	7:12	Y	Double Read
					VISIT 4	08APR2015	7:16	Y	Double Read
					VISIT 6	17AUG2015	7:22	Y	Double Read
					VISIT 7	22FEB2016	7:16	Y	Double Read
					VISIT 8	02FEB2017	7:24	Y	Double Read
					VISIT 11	19MAR2020	8:20	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	3_4		Caudal Disc		Baseline	27NOV2014	7:42	0	Double Read
					VISIT 3A	03MAR2015	7:12	0	Double Read
					VISIT 4	08APR2015	7:16	0	Double Read
					VISIT 6	17AUG2015	7:22	0	Double Read
					VISIT 7	22FEB2016	7:16	0	Double Read
					VISIT 8	02FEB2017	7:24	0	Double Read
					VISIT 11	19MAR2020	8:20	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	3_4		Central Disc		Baseline	27NOV2014	7:42	0	Double Read
					VISIT 3A	03MAR2015	7:12	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	3_4		Central Disc		VISIT 4	08APR2015	7:16	0	Double Read
					VISIT 6	17AUG2015	7:22	0	Double Read
					VISIT 7	22FEB2016	7:16	1	Double Read
					VISIT 8	02FEB2017	7:24	1	Double Read
					VISIT 11	19MAR2020	8:20	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	27NOV2014	7:42	0	Double Read
					VISIT 3A	03MAR2015	7:12	0	Double Read
					VISIT 4	08APR2015	7:16	0	Double Read
					VISIT 6	17AUG2015	7:22	0	Double Read
					VISIT 7	22FEB2016	7:16	0	Double Read
					VISIT 8	02FEB2017	7:24	0	Double Read
Protruding osteophyte (Caudal Disc)	3_4		Caudal Disc		VISIT 11	19MAR2020	8:20	0	Double Read
					Baseline	27NOV2014	7:42	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
					VISIT 7	22FEB2016	7:16	N	Double Read
Protruding osteophyte (Central Disc)	3_4		Central Disc		VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read
					Baseline	27NOV2014	7:42	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		VISIT 7	22FEB2016	7:16	N	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
					VISIT 7	22FEB2016	7:16	N	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read
Relevant scoliosis	3_4		General		Baseline	27NOV2014	7:42	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
					VISIT 7	22FEB2016	7:16	N	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	3_4		Caudal Disc		Baseline	27NOV2014	7:42	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
					VISIT 7	22FEB2016	7:16	N	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	3_4		Central Disc		Baseline	27NOV2014	7:42	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
					VISIT 7	22FEB2016	7:16	N	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	27NOV2014	7:42	N	Double Read
					VISIT 3A	03MAR2015	7:12	N	Double Read
					VISIT 4	08APR2015	7:16	N	Double Read
					VISIT 6	17AUG2015	7:22	N	Double Read
					VISIT 7	22FEB2016	7:16	N	Double Read
					VISIT 8	02FEB2017	7:24	N	Double Read
					VISIT 11	19MAR2020	8:20	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	27NOV2014	7:42	83.7792	Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22	84.63536	Double Read
					VISIT 7	22FEB2016	7:16	87.15376	Double Read
					VISIT 8	02FEB2017	7:24	85.2952	Double Read
					VISIT 11	19MAR2020	8:20	70.18624	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
T2 (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	27NOV2014	7:42	92.268	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22	87.46976	Double Read
					VISIT 7	22FEB2016	7:16	89.59024	Double Read
					VISIT 8	02FEB2017	7:24	84.56912	Double Read
					VISIT 11	19MAR2020	8:20	74.96832	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	27NOV2014	7:42	104.37248	Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22	100.66	Double Read
					VISIT 7	22FEB2016	7:16	100.73712	Double Read
					VISIT 8	02FEB2017	7:24	100.44304	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	19MAR2020	8:20	86.5264	Double Read
					VISIT 3A	03MAR2015	7:12		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	3_4		Caudal Disc		Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	3_4		Central Disc		Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	3_4		Caudal Disc		Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	3_4		Central Disc		Baseline	27NOV2014	7:42	equal	Double Read
					VISIT 3A	03MAR2015	7:12	equal	Double Read
					VISIT 4	08APR2015	7:16	equal	Double Read
					VISIT 6	17AUG2015	7:22	equal	Double Read
					VISIT 7	22FEB2016	7:16	equal	Double Read
					VISIT 8	02FEB2017	7:24	equal	Double Read
					VISIT 11	19MAR2020	8:20	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	3_4		Caudal Disc		Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	3_4		Caudal Disc		VISIT 11	19MAR2020	8:20		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	3_4		Central Disc		Baseline	27NOV2014	7:42	lower	Double Read
					VISIT 3A	03MAR2015	7:12	lower	Double Read
					VISIT 4	08APR2015	7:16	lower	Double Read
					VISIT 6	17AUG2015	7:22	lower	Double Read
					VISIT 7	22FEB2016	7:16	lower	Double Read
					VISIT 8	02FEB2017	7:24	lower	Double Read
					VISIT 11	19MAR2020	8:20	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	3_4		Caudal Disc		Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	3_4		Central Disc		Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	3_4		Central Disc		VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	27NOV2014	7:42	5.97250891796	Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22	10.1070154578	Double Read
					VISIT 7	22FEB2016	7:16	10.0390691354	Double Read
					VISIT 8	02FEB2017	7:24	7.51889926957	Double Read
					VISIT 11	19MAR2020	8:20	6.1935722779	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	27NOV2014	7:42		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
T2_error (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	27NOV2014	7:42	10.4904365551	Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22	10.0004620357	Double Read
					VISIT 7	22FEB2016	7:16	12.0297333107	Double Read
					VISIT 8	02FEB2017	7:24	5.0959741804	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	VISIT 11	19MAR2020	8:20	5.86037030745	Double Read
					Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
					Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	27NOV2014	7:42	3.31238321726	Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22	2.41856293529	Double Read
					VISIT 7	22FEB2016	7:16	5.47817224393	Double Read
					VISIT 8	02FEB2017	7:24	12.3322575166	Double Read
					VISIT 11	19MAR2020	8:20	5.48100560557	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	VISIT 11	19MAR2020	8:20		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	27NOV2014	7:42	12919.0	Double Read
					VISIT 3A	03MAR2015	7:12	13848.0	Double Read
					VISIT 4	08APR2015	7:16	14491.0	Double Read
					VISIT 6	17AUG2015	7:22	14010.5	Double Read
					VISIT 7	22FEB2016	7:16	13383.0	Double Read
					VISIT 8	02FEB2017	7:24	14272.0	Double Read
					VISIT 11	19MAR2020	8:20	12764.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	27NOV2014	7:42	13154.0	Double Read
					VISIT 3A	03MAR2015	7:12	13440.5	Double Read
					VISIT 4	08APR2015	7:16	15324.0	Double Read
					VISIT 6	17AUG2015	7:22	14783.0	Double Read
					VISIT 7	22FEB2016	7:16	12657.0	Double Read
					VISIT 8	02FEB2017	7:24	13401.5	Double Read
					VISIT 11	19MAR2020	8:20	12051.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0802 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
Volume (mm ³) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read
Volume (mm ³) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	27NOV2014	7:42	12620.0	Double Read
					VISIT 3A	03MAR2015	7:12	13009.5	Double Read
					VISIT 4	08APR2015	7:16	13636.5	Double Read
					VISIT 6	17AUG2015	7:22	14214.0	Double Read
					VISIT 7	22FEB2016	7:16	13005.0	Double Read
					VISIT 8	02FEB2017	7:24	13558.0	Double Read
					VISIT 11	19MAR2020	8:20	12499.5	Double Read
Volume (mm ³) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	27NOV2014	7:42		Double Read
					VISIT 3A	03MAR2015	7:12		Double Read
					VISIT 4	08APR2015	7:16		Double Read
					VISIT 6	17AUG2015	7:22		Double Read
					VISIT 7	22FEB2016	7:16		Double Read
					VISIT 8	02FEB2017	7:24		Double Read
					VISIT 11	19MAR2020	8:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0803 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirschmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
Disc degeneration grading (Pfirschmann) (Central Disc)	5_S		Central Disc		Baseline	25FEB2015	7:28	4	Double Read
					VISIT 3A	19JUN2015	8:25	4	Double Read
					VISIT 4	21JUL2015	7:20	3	Double Read
Disc degeneration grading (Pfirschmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25FEB2015	7:28	3	Double Read
					VISIT 3A	19JUN2015	8:25	3	Double Read
					VISIT 4	21JUL2015	7:20	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	25FEB2015	7:28	N	Double Read
					VISIT 3A	19JUN2015	8:25	N	Double Read
					VISIT 4	21JUL2015	7:20	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25FEB2015	7:28	N	Double Read
					VISIT 3A	19JUN2015	8:25	N	Double Read
					VISIT 4	21JUL2015	7:20	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	25FEB2015	7:28	Y	Double Read
					VISIT 3A	19JUN2015	8:25	Y	Double Read
					VISIT 4	21JUL2015	7:20	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0803 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25FEB2015	7:28	N	Double Read
					VISIT 3A	19JUN2015	8:25	N	Double Read
					VISIT 4	21JUL2015	7:20	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	25FEB2015	7:28	N	Double Read
					VISIT 3A	19JUN2015	8:25	N	Double Read
					VISIT 4	21JUL2015	7:20	N	Double Read
Fracture	5_S		General		Baseline	25FEB2015	7:28	N	Double Read
					VISIT 3A	19JUN2015	8:25	N	Double Read
					VISIT 4	21JUL2015	7:20	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25FEB2015	7:28	17.925	Double Read
					VISIT 3A	19JUN2015	8:25	17.655	Double Read
					VISIT 4	21JUL2015	7:20	18.4	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25FEB2015	7:28	17.255	Double Read
					VISIT 3A	19JUN2015	8:25	16.755	Double Read
					VISIT 4	21JUL2015	7:20	17.44	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25FEB2015	7:28	12.3391	Double Read
					VISIT 3A	19JUN2015	8:25	12.07645	Double Read
					VISIT 4	21JUL2015	7:20	12.78335	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0803 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25FEB2015	7:28	15.0197	Double Read
					VISIT 3A	19JUN2015	8:25	15.544	Double Read
					VISIT 4	21JUL2015	7:20	14.90255	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	25FEB2015	7:28	N	Double Read
					VISIT 3A	19JUN2015	8:25	N	Double Read
					VISIT 4	21JUL2015	7:20	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25FEB2015	7:28	N	Double Read
					VISIT 3A	19JUN2015	8:25	N	Double Read
					VISIT 4	21JUL2015	7:20	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	25FEB2015	7:28	N	Double Read
					VISIT 3A	19JUN2015	8:25	N	Double Read
					VISIT 4	21JUL2015	7:20	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25FEB2015	7:28	N	Double Read
					VISIT 3A	19JUN2015	8:25	N	Double Read
					VISIT 4	21JUL2015	7:20	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0803 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	5_S		General		Baseline	25FEB2015	7:28	Y	Double Read
					VISIT 3A	19JUN2015	8:25	Y	Double Read
					VISIT 4	21JUL2015	7:20	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	25FEB2015	7:28	0	Double Read
					VISIT 3A	19JUN2015	8:25	0	Double Read
					VISIT 4	21JUL2015	7:20	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25FEB2015	7:28	0	Double Read
					VISIT 3A	19JUN2015	8:25	0	Double Read
					VISIT 4	21JUL2015	7:20	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	25FEB2015	7:28	N	Double Read
					VISIT 3A	19JUN2015	8:25	N	Double Read
					VISIT 4	21JUL2015	7:20	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25FEB2015	7:28	N	Double Read
					VISIT 3A	19JUN2015	8:25	N	Double Read
					VISIT 4	21JUL2015	7:20	N	Double Read
Relevant scoliosis	5_S		General		Baseline	25FEB2015	7:28	N	Double Read
					VISIT 3A	19JUN2015	8:25	N	Double Read
					VISIT 4	21JUL2015	7:20	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	25FEB2015	7:28		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0803 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	25FEB2015	7:28	N	Double Read
					VISIT 3A	19JUN2015	8:25	N	Double Read
					VISIT 4	21JUL2015	7:20	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25FEB2015	7:28	N	Double Read
					VISIT 3A	19JUN2015	8:25	N	Double Read
					VISIT 4	21JUL2015	7:20	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25FEB2015	7:28	86.85376	Double Read
					VISIT 3A	19JUN2015	8:25	92.00912	Double Read
					VISIT 4	21JUL2015	7:20	91.1616	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0803 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25FEB2015	7:28	84.95136	Double Read
					VISIT 3A	19JUN2015	8:25	93.60688	Double Read
					VISIT 4	21JUL2015	7:20	92.37808	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0803 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	25FEB2015	7:28		Double Read
					VISIT 3A VISIT 4	19JUN2015 21JUL2015	8:25 7:20		Double Read Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	25FEB2015	7:28		Double Read
					VISIT 3A VISIT 4	19JUN2015 21JUL2015	8:25 7:20		Double Read Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	25FEB2015	7:28		Double Read
					VISIT 3A VISIT 4	19JUN2015 21JUL2015	8:25 7:20		Double Read Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	25FEB2015	7:28		Double Read
					VISIT 3A VISIT 4	19JUN2015 21JUL2015	8:25 7:20		Double Read Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	25FEB2015	7:28	lower	Double Read
					VISIT 3A VISIT 4	19JUN2015 21JUL2015	8:25 7:20	equal equal	Double Read Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	25FEB2015	7:28		Double Read
					VISIT 3A VISIT 4	19JUN2015 21JUL2015	8:25 7:20		Double Read Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	25FEB2015	7:28		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0803 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	25FEB2015	7:28		Double Read
					VISIT 3A VISIT 4	19JUN2015 21JUL2015	8:25 7:20		Double Read Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	25FEB2015	7:28		Double Read
					VISIT 3A VISIT 4	19JUN2015 21JUL2015	8:25 7:20		Double Read Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A VISIT 4	19JUN2015 21JUL2015	8:25 7:20		Double Read Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A VISIT 4	19JUN2015 21JUL2015	8:25 7:20		Double Read Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A VISIT 4	19JUN2015 21JUL2015	8:25 7:20		Double Read Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A VISIT 4	19JUN2015 21JUL2015	8:25 7:20		Double Read Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25FEB2015	7:28	7.6424868354	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0803 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	19JUN2015	8:25	7.5711635807	Double Read
					VISIT 4	21JUL2015	7:20	9.7066213691	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25FEB2015	7:28	6.3524375743	Double Read
					VISIT 3A	19JUN2015	8:25	11.140771190	Double Read
					VISIT 4	21JUL2015	7:20	10.866261253	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0803 Age=51 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25FEB2015	7:28	20541.0	Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20	21708.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25FEB2015	7:28	26302.5	Double Read
					VISIT 3A	19JUN2015	8:25	25689.0	Double Read
					VISIT 4	21JUL2015	7:20	27147.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	25FEB2015	7:28		Double Read
					VISIT 3A	19JUN2015	8:25		Double Read
					VISIT 4	21JUL2015	7:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	3_4		Caudal Disc		Baseline	03JUN2015	7:36	3	Double Read
					VISIT 3A	20AUG2015	7:37	3	Double Read
					VISIT 4	28SEP2015	8:02	4	Double Read
					VISIT 6	05FEB2016	8:38	4	Double Read
					VISIT 7	22AUG2016	7:12	3	Double Read
					VISIT 8	04AUG2017	9:03	4	Double Read
					VISIT 11	04AUG2020	8:38	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	3_4		Central Disc		Baseline	03JUN2015	7:36	3	Double Read
					VISIT 3A	20AUG2015	7:37	3	Double Read
					VISIT 4	28SEP2015	8:02	3	Double Read
					VISIT 6	05FEB2016	8:38	3	Double Read
					VISIT 7	22AUG2016	7:12	3	Double Read
					VISIT 8	04AUG2017	9:03	3	Double Read
					VISIT 11	04AUG2020	8:38	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	03JUN2015	7:36	2	Double Read
					VISIT 3A	20AUG2015	7:37	2	Double Read
					VISIT 4	28SEP2015	8:02	2	Double Read
					VISIT 6	05FEB2016	8:38	2	Double Read
					VISIT 7	22AUG2016	7:12	2	Double Read
					VISIT 8	04AUG2017	9:03	2	Double Read
					VISIT 11	04AUG2020	8:38	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	3_4		Caudal Disc		Baseline	03JUN2015	7:36	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	3_4		Central Disc		Baseline	03JUN2015	7:36	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	3_4		Central Disc		VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	03JUN2015	7:36	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	N	Double Read
Dorsal disc extrusion (Caudal Disc)	3_4		Caudal Disc		VISIT 11	04AUG2020	8:38	N	Double Read
					Baseline	03JUN2015	7:36	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read
Dorsal disc extrusion (Central Disc)	3_4		Central Disc		VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	Y	Double Read
					Baseline	03JUN2015	7:36	Y	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	Y	Double Read
					VISIT 6	05FEB2016	8:38	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read
					Baseline	03JUN2015	7:36	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read
Extradiscal fluid collection	3_4		General		Baseline	03JUN2015	7:36	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read
Fracture	3_4		General		Baseline	03JUN2015	7:36	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	03JUN2015	7:36	14.645	Double Read
					VISIT 3A	20AUG2015	7:37	15.755	Double Read
					VISIT 4	28SEP2015	8:02	14.335	Double Read
					VISIT 6	05FEB2016	8:38	16.435	Double Read
					VISIT 7	22AUG2016	7:12	14.87	Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38	15.335	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	03JUN2015	7:36	14.685	Double Read
					VISIT 3A	20AUG2015	7:37	14.53	Double Read
					VISIT 4	28SEP2015	8:02	15.795	Double Read
					VISIT 6	05FEB2016	8:38	14.905	Double Read
					VISIT 7	22AUG2016	7:12	15.09	Double Read
					VISIT 8	04AUG2017	9:03	14.63	Double Read
					VISIT 11	04AUG2020	8:38	14.81	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	03JUN2015	7:36	13.315	Double Read
					VISIT 3A	20AUG2015	7:37	15.82	Double Read
					VISIT 4	28SEP2015	8:02	13.91	Double Read
					VISIT 6	05FEB2016	8:38	14.345	Double Read
					VISIT 7	22AUG2016	7:12	14.69	Double Read
					VISIT 8	04AUG2017	9:03	14.18	Double Read
					VISIT 11	04AUG2020	8:38	13.76	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	03JUN2015	7:36	11.543	Double Read
					VISIT 3A	20AUG2015	7:37	10.7855	Double Read
					VISIT 4	28SEP2015	8:02	12.3751	Double Read
					VISIT 6	05FEB2016	8:38	11.8776	Double Read
					VISIT 7	22AUG2016	7:12	12.60105	Double Read
					VISIT 8	04AUG2017	9:03	11.5028	Double Read
					VISIT 11	04AUG2020	8:38	11.8338	Double Read
Height manual (mm) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	03JUN2015	7:36	11.52315	Double Read
					VISIT 3A	20AUG2015	7:37	11.2533	Double Read
					VISIT 4	28SEP2015	8:02	12.18975	Double Read
					VISIT 6	05FEB2016	8:38	11.3108	Double Read
					VISIT 7	22AUG2016	7:12	11.107635	Double Read
					VISIT 8	04AUG2017	9:03	9.867495	Double Read
					VISIT 11	04AUG2020	8:38	10.19475	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	03JUN2015	7:36	12.99075	Double Read
					VISIT 3A	20AUG2015	7:37	11.1524	Double Read
					VISIT 4	28SEP2015	8:02	11.29245	Double Read
					VISIT 6	05FEB2016	8:38	12.5576	Double Read
					VISIT 7	22AUG2016	7:12	11.8175	Double Read
					VISIT 8	04AUG2017	9:03	10.7809	Double Read
					VISIT 11	04AUG2020	8:38	12.45245	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	3_4		Caudal Disc		Baseline	03JUN2015	7:36	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	3_4		Central Disc		Baseline	03JUN2015	7:36	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	03JUN2015	7:36	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	3_4		Caudal Disc		Baseline	03JUN2015	7:36	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	3_4		Central Disc		Baseline	03JUN2015	7:36	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	03JUN2015	7:36	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read
Normal lordotic LS	3_4		General		Baseline	03JUN2015	7:36	Y	Double Read
					VISIT 3A	20AUG2015	7:37	Y	Double Read
					VISIT 4	28SEP2015	8:02	Y	Double Read
					VISIT 6	05FEB2016	8:38	Y	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	Y	Double Read
					VISIT 11	04AUG2020	8:38	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	3_4		Caudal Disc		Baseline	03JUN2015	7:36	0	Double Read
					VISIT 3A	20AUG2015	7:37	0	Double Read
					VISIT 4	28SEP2015	8:02	0	Double Read
					VISIT 6	05FEB2016	8:38	0	Double Read
					VISIT 7	22AUG2016	7:12	0	Double Read
					VISIT 8	04AUG2017	9:03	0	Double Read
					VISIT 11	04AUG2020	8:38	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	3_4		Central Disc		Baseline	03JUN2015	7:36	0	Double Read
					VISIT 3A	20AUG2015	7:37	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	3_4		Central Disc		VISIT 4	28SEP2015	8:02	0	Double Read
					VISIT 6	05FEB2016	8:38	0	Double Read
					VISIT 7	22AUG2016	7:12	0	Double Read
					VISIT 8	04AUG2017	9:03	0	Double Read
					VISIT 11	04AUG2020	8:38	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	03JUN2015	7:36	0	Double Read
					VISIT 3A	20AUG2015	7:37	0	Double Read
					VISIT 4	28SEP2015	8:02	0	Double Read
					VISIT 6	05FEB2016	8:38	0	Double Read
					VISIT 7	22AUG2016	7:12	0	Double Read
					VISIT 8	04AUG2017	9:03	0	Double Read
Protruding osteophyte (Caudal Disc)	3_4		Caudal Disc		VISIT 11	04AUG2020	8:38	0	Double Read
					Baseline	03JUN2015	7:36	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read
Protruding osteophyte (Central Disc)	3_4		Central Disc		VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read
					Baseline	03JUN2015	7:36	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read
Relevant scoliosis	3_4		General		Baseline	03JUN2015	7:36	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	3_4		Caudal Disc		Baseline	03JUN2015	7:36	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	3_4		Central Disc		Baseline	03JUN2015	7:36	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	03JUN2015	7:36	N	Double Read
					VISIT 3A	20AUG2015	7:37	N	Double Read
					VISIT 4	28SEP2015	8:02	N	Double Read
					VISIT 6	05FEB2016	8:38	N	Double Read
					VISIT 7	22AUG2016	7:12	N	Double Read
					VISIT 8	04AUG2017	9:03	N	Double Read
					VISIT 11	04AUG2020	8:38	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	03JUN2015	7:36	80.152	Double Read
					VISIT 3A	20AUG2015	7:37	88.72992	Double Read
					VISIT 4	28SEP2015	8:02	90.9984	Double Read
					VISIT 6	05FEB2016	8:38	90.1408	Double Read
					VISIT 7	22AUG2016	7:12	91.99184	Double Read
					VISIT 8	04AUG2017	9:03	83.06704	Double Read
					VISIT 11	04AUG2020	8:38		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
T2 (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	03JUN2015	7:36	90.09184	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	VISIT 3A	20AUG2015	7:37	90.4392	Double Read
					VISIT 4	28SEP2015	8:02	94.39328	Double Read
					VISIT 6	05FEB2016	8:38	94.43504	Double Read
					VISIT 7	22AUG2016	7:12	102.13936	Double Read
					VISIT 8	04AUG2017	9:03	91.77216	Double Read
					VISIT 11	04AUG2020	8:38		Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	VISIT 11	04AUG2020	8:38		Double Read
					Baseline	03JUN2015	7:36	95.40928	Double Read
					VISIT 3A	20AUG2015	7:37	100.17472	Double Read
					VISIT 4	28SEP2015	8:02	98.34192	Double Read
					VISIT 6	05FEB2016	8:38	106.71168	Double Read
					VISIT 7	22AUG2016	7:12	98.3496	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	04AUG2017	9:03	93.84032	Double Read
					VISIT 11	04AUG2020	8:38		Double Read
					Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	3_4		Caudal Disc		Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	3_4		Central Disc		Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	3_4		Caudal Disc		Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	3_4		Central Disc		Baseline	03JUN2015	7:36	higher	Double Read
					VISIT 3A	20AUG2015	7:37	higher	Double Read
					VISIT 4	28SEP2015	8:02	higher	Double Read
					VISIT 6	05FEB2016	8:38	higher	Double Read
					VISIT 7	22AUG2016	7:12	higher	Double Read
					VISIT 8	04AUG2017	9:03	higher	Double Read
					VISIT 11	04AUG2020	8:38	equal	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	3_4		Caudal Disc		Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	3_4		Caudal Disc		VISIT 11	04AUG2020	8:38		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	3_4		Central Disc		Baseline	03JUN2015	7:36	lower	Double Read
					VISIT 3A	20AUG2015	7:37	lower	Double Read
					VISIT 4	28SEP2015	8:02	lower	Double Read
					VISIT 6	05FEB2016	8:38	lower	Double Read
					VISIT 7	22AUG2016	7:12	lower	Double Read
					VISIT 8	04AUG2017	9:03	lower	Double Read
					VISIT 11	04AUG2020	8:38	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	3_4		Caudal Disc		Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	3_4		Central Disc		Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	3_4		Central Disc		VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	03JUN2015	7:36	5.8060879904	Double Read
					VISIT 3A	20AUG2015	7:37	7.6139833531	Double Read
					VISIT 4	28SEP2015	8:02	9.1789298454	Double Read
					VISIT 6	05FEB2016	8:38	8.4663291999	Double Read
					VISIT 7	22AUG2016	7:12	11.298576524	Double Read
					VISIT 8	04AUG2017	9:03	6.8069577034	Double Read
					VISIT 11	04AUG2020	8:38		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
T2_error (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	03JUN2015	7:36	7.8817733990	Double Read
					VISIT 3A	20AUG2015	7:37	9.3786512655	Double Read
					VISIT 4	28SEP2015	8:02	7.3495294717	Double Read
					VISIT 6	05FEB2016	8:38	10.578861899	Double Read
					VISIT 7	22AUG2016	7:12	10.849838627	Double Read
					VISIT 8	04AUG2017	9:03	9.2900424664	Double Read
					VISIT 11	04AUG2020	8:38		Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	VISIT 11	04AUG2020	8:38		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	03JUN2015	7:36	14.0220146085	Double Read
					VISIT 3A	20AUG2015	7:37	4.31034482759	Double Read
					VISIT 4	28SEP2015	8:02	14.545792424	Double Read
					VISIT 6	05FEB2016	8:38	13.7839986411	Double Read
					VISIT 7	22AUG2016	7:12	12.6646441311	Double Read
					VISIT 8	04AUG2017	9:03	9.64009512486	Double Read
					VISIT 11	04AUG2020	8:38		Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	03JUN2015	7:36	24148.5	Double Read
					VISIT 3A	20AUG2015	7:37	25588.5	Double Read
					VISIT 4	28SEP2015	8:02	25028.0	Double Read
					VISIT 6	05FEB2016	8:38	25697.0	Double Read
					VISIT 7	22AUG2016	7:12	26015.0	Double Read
					VISIT 8	04AUG2017	9:03		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	VISIT 11	04AUG2020	8:38	26023.5	Double Read
					Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
					Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
					Baseline	03JUN2015	7:36	25321.5	Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02	26805.5	Double Read
					VISIT 6	05FEB2016	8:38	28603.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	VISIT 7	22AUG2016	7:12	28146.0	Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38	26239.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	03JUN2015	7:36	22450.5	Double Read
					VISIT 3A	20AUG2015	7:37	25954.0	Double Read
					VISIT 4	28SEP2015	8:02	24862.5	Double Read
					VISIT 6	05FEB2016	8:38	24394.0	Double Read
					VISIT 7	22AUG2016	7:12	25579.5	Double Read
					VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38	24414.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	03JUN2015	7:36		Double Read
					VISIT 3A	20AUG2015	7:37		Double Read
					VISIT 4	28SEP2015	8:02		Double Read
					VISIT 6	05FEB2016	8:38		Double Read
					VISIT 7	22AUG2016	7:12		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0804 Age=49 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	04AUG2017	9:03		Double Read
					VISIT 11	04AUG2020	8:38		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	2_3		Caudal Disc		Baseline	24JUN2015	7:15	2	Double Read
					VISIT 3A	21SEP2015	7:20	3	Double Read
					VISIT 4	02NOV2015	7:22	3	Double Read
					VISIT 6	07MAR2016	7:14	3	Double Read
					VISIT 7	14FEB2017	7:21	3	Double Read
					VISIT 8	28AUG2017	8:10	3	Double Read
					VISIT 11	03SEP2020	7:09	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	2_3		Central Disc		Baseline	24JUN2015	7:15	2	Double Read
					VISIT 3A	21SEP2015	7:20	3	Double Read
					VISIT 4	02NOV2015	7:22	3	Double Read
					VISIT 6	07MAR2016	7:14	3	Double Read
					VISIT 7	14FEB2017	7:21	3	Double Read
					VISIT 8	28AUG2017	8:10	3	Double Read
					VISIT 11	03SEP2020	7:09	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		Baseline	24JUN2015	7:15	2	Double Read
					VISIT 3A	21SEP2015	7:20	2	Double Read
					VISIT 4	02NOV2015	7:22	2	Double Read
					VISIT 6	07MAR2016	7:14	2	Double Read
					VISIT 7	14FEB2017	7:21	2	Double Read
					VISIT 8	28AUG2017	8:10	2	Double Read
					VISIT 11	03SEP2020	7:09	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	2_3		Caudal Disc		Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
					VISIT 7	14FEB2017	7:21	N	Double Read
					VISIT 8	28AUG2017	8:10	N	Double Read
					VISIT 11	03SEP2020	7:09	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	2_3		Central Disc		Baseline	24JUN2015	7:15	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	2_3		Central Disc		VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
					VISIT 7	14FEB2017	7:21	N	Double Read
					VISIT 8	28AUG2017	8:10	N	Double Read
					VISIT 11	03SEP2020	7:09	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
					VISIT 7	14FEB2017	7:21	N	Double Read
					VISIT 8	28AUG2017	8:10	N	Double Read
Dorsal disc extrusion (Caudal Disc)	2_3		Caudal Disc		VISIT 11	03SEP2020	7:09	N	Double Read
					Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
					VISIT 7	14FEB2017	7:21	N	Double Read
Dorsal disc extrusion (Central Disc)	2_3		Central Disc		VISIT 8	28AUG2017	8:10	N	Double Read
					VISIT 11	03SEP2020	7:09	N	Double Read
					Baseline	24JUN2015	7:15	Y	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		VISIT 7	14FEB2017	7:21	Y	Double Read
					VISIT 8	28AUG2017	8:10	N	Double Read
					VISIT 11	03SEP2020	7:09	N	Double Read
					Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		VISIT 7	14FEB2017	7:21	N	Double Read
					VISIT 8	28AUG2017	8:10	N	Double Read
					VISIT 11	03SEP2020	7:09	N	Double Read
Extradiscal fluid collection	2_3		General		Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
					VISIT 7	14FEB2017	7:21	N	Double Read
					VISIT 8	28AUG2017	8:10	N	Double Read
					VISIT 11	03SEP2020	7:09	N	Double Read
Fracture	2_3		General		Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
					VISIT 7	14FEB2017	7:21	N	Double Read
					VISIT 8	28AUG2017	8:10	N	Double Read
					VISIT 11	03SEP2020	7:09	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	2_3		Caudal Disc	Complete Disc	Baseline	24JUN2015	7:15	12.725	Double Read
					VISIT 3A	21SEP2015	7:20	13.22	Double Read
					VISIT 4	02NOV2015	7:22	14.0	Double Read
					VISIT 6	07MAR2016	7:14	12.58	Double Read
					VISIT 7	14FEB2017	7:21	13.08	Double Read
					VISIT 8	28AUG2017	8:10	13.405	Double Read
					VISIT 11	03SEP2020	7:09	11.47	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	2_3		Central Disc	Complete Disc	Baseline	24JUN2015	7:15	11.77	Double Read
					VISIT 3A	21SEP2015	7:20	12.27	Double Read
					VISIT 4	02NOV2015	7:22	11.98	Double Read
					VISIT 6	07MAR2016	7:14	11.295	Double Read
					VISIT 7	14FEB2017	7:21	10.7	Double Read
					VISIT 8	28AUG2017	8:10	12.1	Double Read
					VISIT 11	03SEP2020	7:09	12.06	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	2_3		Cranial Disc, not treated	Complete Disc	Baseline	24JUN2015	7:15	11.93	Double Read
					VISIT 3A	21SEP2015	7:20	11.96	Double Read
					VISIT 4	02NOV2015	7:22	13.44	Double Read
					VISIT 6	07MAR2016	7:14	12.735	Double Read
					VISIT 7	14FEB2017	7:21	13.1	Double Read
					VISIT 8	28AUG2017	8:10	12.895	Double Read
					VISIT 11	03SEP2020	7:09	12.37	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	2_3		Caudal Disc	Complete Disc	Baseline	24JUN2015	7:15	10.86595	Double Read
					VISIT 3A	21SEP2015	7:20	11.21575	Double Read
					VISIT 4	02NOV2015	7:22	11.6236	Double Read
					VISIT 6	07MAR2016	7:14	11.3663	Double Read
					VISIT 7	14FEB2017	7:21	10.35816	Double Read
					VISIT 8	28AUG2017	8:10	9.95547	Double Read
					VISIT 11	03SEP2020	7:09	9.688325	Double Read
Height manual (mm) (Central Disc, Complete Disc)	2_3		Central Disc	Complete Disc	Baseline	24JUN2015	7:15	10.119665	Double Read
					VISIT 3A	21SEP2015	7:20	8.63935	Double Read
					VISIT 4	02NOV2015	7:22	9.041425	Double Read
					VISIT 6	07MAR2016	7:14	9.048185	Double Read
					VISIT 7	14FEB2017	7:21	7.297795	Double Read
					VISIT 8	28AUG2017	8:10	7.75342	Double Read
					VISIT 11	03SEP2020	7:09	7.085685	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	2_3		Cranial Disc, not treated	Complete Disc	Baseline	24JUN2015	7:15	9.415975	Double Read
					VISIT 3A	21SEP2015	7:20	9.671155	Double Read
					VISIT 4	02NOV2015	7:22	9.99928	Double Read
					VISIT 6	07MAR2016	7:14	10.5169	Double Read
					VISIT 7	14FEB2017	7:21	9.394175	Double Read
					VISIT 8	28AUG2017	8:10	8.97961	Double Read
					VISIT 11	03SEP2020	7:09	9.86105	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	2_3		Caudal Disc		Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
					VISIT 7	14FEB2017	7:21	N	Double Read
					VISIT 8	28AUG2017	8:10	N	Double Read
					VISIT 11	03SEP2020	7:09	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	2_3		Central Disc		Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
					VISIT 7	14FEB2017	7:21	N	Double Read
					VISIT 8	28AUG2017	8:10	N	Double Read
					VISIT 11	03SEP2020	7:09	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
					VISIT 7	14FEB2017	7:21	N	Double Read
					VISIT 8	28AUG2017	8:10	N	Double Read
					VISIT 11	03SEP2020	7:09	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	2_3		Caudal Disc		Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
					VISIT 7	14FEB2017	7:21	N	Double Read
					VISIT 8	28AUG2017	8:10	N	Double Read
					VISIT 11	03SEP2020	7:09	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	2_3		Central Disc		Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
					VISIT 7	14FEB2017	7:21	N	Double Read
					VISIT 8	28AUG2017	8:10	N	Double Read
					VISIT 11	03SEP2020	7:09	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
					VISIT 7	14FEB2017	7:21	N	Double Read
					VISIT 8	28AUG2017	8:10	N	Double Read
					VISIT 11	03SEP2020	7:09	N	Double Read
Normal lordotic LS	2_3		General		Baseline	24JUN2015	7:15	Y	Double Read
					VISIT 3A	21SEP2015	7:20	Y	Double Read
					VISIT 4	02NOV2015	7:22	Y	Double Read
					VISIT 6	07MAR2016	7:14	Y	Double Read
					VISIT 7	14FEB2017	7:21	Y	Double Read
					VISIT 8	28AUG2017	8:10	Y	Double Read
					VISIT 11	03SEP2020	7:09	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	2_3		Caudal Disc		Baseline	24JUN2015	7:15	0	Double Read
					VISIT 3A	21SEP2015	7:20	0	Double Read
					VISIT 4	02NOV2015	7:22	0	Double Read
					VISIT 6	07MAR2016	7:14	0	Double Read
					VISIT 7	14FEB2017	7:21	0	Double Read
					VISIT 8	28AUG2017	8:10	0	Double Read
					VISIT 11	03SEP2020	7:09	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	2_3		Central Disc		Baseline	24JUN2015	7:15	0	Double Read
					VISIT 3A	21SEP2015	7:20	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	2_3		Central Disc		VISIT 4	02NOV2015	7:22	0	Double Read
					VISIT 6	07MAR2016	7:14	0	Double Read
					VISIT 7	14FEB2017	7:21	0	Double Read
					VISIT 8	28AUG2017	8:10	0	Double Read
					VISIT 11	03SEP2020	7:09	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		Baseline	24JUN2015	7:15	0	Double Read
					VISIT 3A	21SEP2015	7:20	0	Double Read
					VISIT 4	02NOV2015	7:22	0	Double Read
					VISIT 6	07MAR2016	7:14	0	Double Read
					VISIT 7	14FEB2017	7:21	0	Double Read
					VISIT 8	28AUG2017	8:10	0	Double Read
Protruding osteophyte (Caudal Disc)	2_3		Caudal Disc		VISIT 11	03SEP2020	7:09	0	Double Read
					Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
					VISIT 7	14FEB2017	7:21	N	Double Read
Protruding osteophyte (Central Disc)	2_3		Central Disc		VISIT 8	28AUG2017	8:10	N	Double Read
					VISIT 11	03SEP2020	7:09	N	Double Read
					Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		VISIT 7	14FEB2017	7:21	N	Double Read
					VISIT 8	28AUG2017	8:10	N	Double Read
					VISIT 11	03SEP2020	7:09	N	Double Read
					Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
					VISIT 7	14FEB2017	7:21	N	Double Read
					VISIT 8	28AUG2017	8:10	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		VISIT 8	28AUG2017	8:10	N	Double Read
					VISIT 11	03SEP2020	7:09	N	Double Read
Relevant scoliosis	2_3		General		Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
					VISIT 7	14FEB2017	7:21	N	Double Read
					VISIT 8	28AUG2017	8:10	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	2_3		Caudal Disc		VISIT 11	03SEP2020	7:09	N	Double Read
					Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
					VISIT 7	14FEB2017	7:21	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	2_3		Central Disc		VISIT 8	28AUG2017	8:10	N	Double Read
					VISIT 11	03SEP2020	7:09	N	Double Read
					Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read
					VISIT 6	07MAR2016	7:14	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		VISIT 7	14FEB2017	7:21	N	Double Read
					VISIT 8	28AUG2017	8:10	N	Double Read
					VISIT 11	03SEP2020	7:09	N	Double Read
					Baseline	24JUN2015	7:15	N	Double Read
					VISIT 3A	21SEP2015	7:20	N	Double Read
					VISIT 4	02NOV2015	7:22	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	2_3		Caudal Disc	Anulus Fibrosus	Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	2_3		Caudal Disc	Complete Disc	Baseline	24JUN2015	7:15	96.17696	Double Read
					VISIT 3A	21SEP2015	7:20	89.92928	Double Read
					VISIT 4	02NOV2015	7:22	90.1784	Double Read
					VISIT 6	07MAR2016	7:14	95.55136	Double Read
					VISIT 7	14FEB2017	7:21	93.38512	Double Read
					VISIT 8	28AUG2017	8:10	89.24144	Double Read
					VISIT 11	03SEP2020	7:09	79.3312	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	2_3		Caudal Disc	Nucleus Pulposus	Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	2_3		Central Disc	Anulus Fibrosus	Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read
T2 (ms) (Central Disc, Complete Disc)	2_3		Central Disc	Complete Disc	Baseline	24JUN2015	7:15	97.57856	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	2_3		Central Disc	Complete Disc	VISIT 3A	21SEP2015	7:20	89.76336	Double Read
					VISIT 4	02NOV2015	7:22	92.42864	Double Read
					VISIT 6	07MAR2016	7:14	97.8168	Double Read
					VISIT 7	14FEB2017	7:21	106.48336	Double Read
					VISIT 8	28AUG2017	8:10	103.6192	Double Read
					VISIT 11	03SEP2020	7:09	81.9568	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	2_3		Central Disc	Nucleus Pulposus	Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	2_3		Cranial Disc, not treated	Anulus Fibrosus	Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	2_3		Cranial Disc, not treated	Complete Disc	Baseline	24JUN2015	7:15	101.2048	Double Read
					VISIT 3A	21SEP2015	7:20	97.4304	Double Read
					VISIT 4	02NOV2015	7:22	97.45264	Double Read
					VISIT 6	07MAR2016	7:14	107.50736	Double Read
					VISIT 7	14FEB2017	7:21	97.21984	Double Read
					VISIT 8	28AUG2017	8:10	93.96672	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	2_3		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	03SEP2020	7:09	82.25088	Double Read
					VISIT 3A	21SEP2015	7:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	2_3		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	2_3		Caudal Disc		Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	2_3		Central Disc		Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	2_3		Cranial Disc, not treated		Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	2_3		Caudal Disc		Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	2_3		Central Disc		Baseline	24JUN2015	7:15	equal	Double Read
					VISIT 3A	21SEP2015	7:20	equal	Double Read
					VISIT 4	02NOV2015	7:22	equal	Double Read
					VISIT 6	07MAR2016	7:14	equal	Double Read
					VISIT 7	14FEB2017	7:21	equal	Double Read
					VISIT 8	28AUG2017	8:10	lower	Double Read
					VISIT 11	03SEP2020	7:09	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	2_3		Cranial Disc, not treated		Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	2_3		Caudal Disc		Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 8	28AUG2017	8:10		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	2_3		Caudal Disc		VISIT 11	03SEP2020	7:09		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	2_3		Central Disc		Baseline	24JUN2015	7:15	lower	Double Read
					VISIT 3A	21SEP2015	7:20	lower	Double Read
					VISIT 4	02NOV2015	7:22	lower	Double Read
					VISIT 6	07MAR2016	7:14	lower	Double Read
					VISIT 7	14FEB2017	7:21	lower	Double Read
					VISIT 8	28AUG2017	8:10	lower	Double Read
					VISIT 11	03SEP2020	7:09	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	2_3		Cranial Disc, not treated		Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	2_3		Caudal Disc		Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	2_3		Central Disc		Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	2_3		Central Disc		VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	2_3		Cranial Disc, not treated		Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	2_3		Caudal Disc	Anulus Fibrosus	Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	2_3		Caudal Disc	Complete Disc	Baseline	24JUN2015	7:15	9.9032852047	Double Read
					VISIT 3A	21SEP2015	7:20	7.27192118227	Double Read
					VISIT 4	02NOV2015	7:22	7.55309665364	Double Read
					VISIT 6	07MAR2016	7:14	7.21935790725	Double Read
					VISIT 7	14FEB2017	7:21	13.2268863598	Double Read
					VISIT 8	28AUG2017	8:10	7.30422965857	Double Read
					VISIT 11	03SEP2020	7:09	8.1226770851	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	2_3		Caudal Disc	Nucleus Pulposus	Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	2_3		Central Disc	Anulus Fibrosus	Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read
T2_error (ms) (Central Disc, Complete Disc)	2_3		Central Disc	Complete Disc	Baseline	24JUN2015	7:15	8.7160047562	Double Read
					VISIT 3A	21SEP2015	7:20	4.2071887209	Double Read
					VISIT 4	02NOV2015	7:22	7.8068150161	Double Read
					VISIT 6	07MAR2016	7:14	13.468469509	Double Read
					VISIT 7	14FEB2017	7:21	4.7675692203	Double Read
					VISIT 8	28AUG2017	8:10	5.6395447596	Double Read
					VISIT 11	03SEP2020	7:09	6.3423271615	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	2_3		Central Disc	Nucleus Pulposus	Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	2_3		Central Disc	Nucleus Pulposus	VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	2_3		Cranial Disc, not treated	Anulus Fibrosus	Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	2_3		Cranial Disc, not treated	Complete Disc	Baseline	24JUN2015	7:15	6.2947375573	Double Read
					VISIT 3A	21SEP2015	7:20	14.7688805844	Double Read
					VISIT 4	02NOV2015	7:22	9.56061151691	Double Read
					VISIT 6	07MAR2016	7:14	11.1080142688	Double Read
					VISIT 7	14FEB2017	7:21	3.61099371496	Double Read
					VISIT 8	28AUG2017	8:10	11.5835841685	Double Read
					VISIT 11	03SEP2020	7:09	12.5511805674	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	2_3		Cranial Disc, not treated	Nucleus Pulposus	Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	2_3		Caudal Disc	Anulus Fibrosus	Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	2_3		Caudal Disc	Complete Disc	Baseline	24JUN2015	7:15	15512.5	Double Read
					VISIT 3A	21SEP2015	7:20	16275.5	Double Read
					VISIT 4	02NOV2015	7:22	17587.5	Double Read
					VISIT 6	07MAR2016	7:14	17153.0	Double Read
					VISIT 7	14FEB2017	7:21	16674.5	Double Read
					VISIT 8	28AUG2017	8:10	15857.5	Double Read
					VISIT 11	03SEP2020	7:09	16025.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	2_3		Caudal Disc	Nucleus Pulposus	Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	2_3		Central Disc	Anulus Fibrosus	Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	2_3		Central Disc	Complete Disc	Baseline	24JUN2015	7:15	14002.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	2_3		Central Disc	Complete Disc	VISIT 3A	21SEP2015	7:20	14257.5	Double Read
					VISIT 4	02NOV2015	7:22	15363.5	Double Read
					VISIT 6	07MAR2016	7:14	14563.5	Double Read
					VISIT 7	14FEB2017	7:21	12639.0	Double Read
					VISIT 8	28AUG2017	8:10	13198.5	Double Read
					VISIT 11	03SEP2020	7:09	13337.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	2_3		Central Disc	Nucleus Pulposus	Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	2_3		Cranial Disc, not treated	Anulus Fibrosus	Baseline	24JUN2015	7:15		Double Read
					VISIT 3A	21SEP2015	7:20		Double Read
					VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	2_3		Cranial Disc, not treated	Complete Disc	Baseline	24JUN2015	7:15	12368.0	Double Read
					VISIT 3A	21SEP2015	7:20	12778.0	Double Read
					VISIT 4	02NOV2015	7:22	13916.5	Double Read
					VISIT 6	07MAR2016	7:14	14094.0	Double Read
					VISIT 7	14FEB2017	7:21	12873.5	Double Read
					VISIT 8	28AUG2017	8:10	14173.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	2_3		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	03SEP2020	7:09	14052.5	Double Read
					VISIT 3A	21SEP2015	7:20		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0805 Age=47 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	2_3		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	02NOV2015	7:22		Double Read
					VISIT 6	07MAR2016	7:14		Double Read
					VISIT 7	14FEB2017	7:21		Double Read
					VISIT 8	28AUG2017	8:10		Double Read
					VISIT 11	03SEP2020	7:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	2_3		Caudal Disc		Baseline	08JUL2015	7:40	4	Double Read
					VISIT 3A	28SEP2015	7:09	4	Double Read
					VISIT 4	06NOV2015	8:22	4	Double Read
					VISIT 6	14MAR2016	7:23	4	Double Read
					VISIT 7	27SEP2016	7:00	4	Double Read
					VISIT 8	12OCT2017	8:24	4	Double Read
					VISIT 11	24SEP2020	8:50	4	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	2_3		Central Disc		Baseline	08JUL2015	7:40	3	Double Read
					VISIT 3A	28SEP2015	7:09	4	Double Read
					VISIT 4	06NOV2015	8:22	4	Double Read
					VISIT 6	14MAR2016	7:23	4	Double Read
					VISIT 7	27SEP2016	7:00	4	Double Read
					VISIT 8	12OCT2017	8:24	4	Double Read
					VISIT 11	24SEP2020	8:50	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		Baseline	08JUL2015	7:40	2	Double Read
					VISIT 3A	28SEP2015	7:09	3	Double Read
					VISIT 4	06NOV2015	8:22	3	Double Read
					VISIT 6	14MAR2016	7:23	3	Double Read
					VISIT 7	27SEP2016	7:00	3	Double Read
					VISIT 8	12OCT2017	8:24	3	Double Read
					VISIT 11	24SEP2020	8:50	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	2_3		Caudal Disc		Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	2_3		Central Disc		Baseline	08JUL2015	7:40	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	2_3		Central Disc		VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
Dorsal disc extrusion (Caudal Disc)	2_3		Caudal Disc		VISIT 11	24SEP2020	8:50	N	Double Read
					Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	Y	Double Read
Dorsal disc extrusion (Central Disc)	2_3		Central Disc		VISIT 8	12OCT2017	8:24	Y	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
					Baseline	08JUL2015	7:40	Y	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		VISIT 7	27SEP2016	7:00	Y	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
					Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
Extradiscal fluid collection	2_3		General		Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
Fracture	2_3		General		Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	2_3		Caudal Disc	Complete Disc	Baseline	08JUL2015	7:40	11.365	Double Read
					VISIT 3A	28SEP2015	7:09	12.935	Double Read
					VISIT 4	06NOV2015	8:22	12.3	Double Read
					VISIT 6	14MAR2016	7:23	13.13	Double Read
					VISIT 7	27SEP2016	7:00	12.815	Double Read
					VISIT 8	12OCT2017	8:24	11.475	Double Read
					VISIT 11	24SEP2020	8:50	13.71	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	2_3		Central Disc	Complete Disc	Baseline	08JUL2015	7:40	12.475	Double Read
					VISIT 3A	28SEP2015	7:09	12.73	Double Read
					VISIT 4	06NOV2015	8:22	14.06	Double Read
					VISIT 6	14MAR2016	7:23	13.3	Double Read
					VISIT 7	27SEP2016	7:00	13.355	Double Read
					VISIT 8	12OCT2017	8:24	13.17	Double Read
					VISIT 11	24SEP2020	8:50	12.565	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	2_3		Cranial Disc, not treated	Complete Disc	Baseline	08JUL2015	7:40	11.525	Double Read
					VISIT 3A	28SEP2015	7:09	13.365	Double Read
					VISIT 4	06NOV2015	8:22	12.96	Double Read
					VISIT 6	14MAR2016	7:23	13.31	Double Read
					VISIT 7	27SEP2016	7:00	12.155	Double Read
					VISIT 8	12OCT2017	8:24	13.205	Double Read
					VISIT 11	24SEP2020	8:50	13.065	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	2_3		Caudal Disc	Complete Disc	Baseline	08JUL2015	7:40	8.882355	Double Read
					VISIT 3A	28SEP2015	7:09	9.25472	Double Read
					VISIT 4	06NOV2015	8:22	9.89795	Double Read
					VISIT 6	14MAR2016	7:23	9.924285	Double Read
					VISIT 7	27SEP2016	7:00	9.378825	Double Read
					VISIT 8	12OCT2017	8:24	9.343355	Double Read
					VISIT 11	24SEP2020	8:50	9.663765	Double Read
Height manual (mm) (Central Disc, Complete Disc)	2_3		Central Disc	Complete Disc	Baseline	08JUL2015	7:40	10.39749	Double Read
					VISIT 3A	28SEP2015	7:09	10.268025	Double Read
					VISIT 4	06NOV2015	8:22	10.37886	Double Read
					VISIT 6	14MAR2016	7:23	10.030685	Double Read
					VISIT 7	27SEP2016	7:00	9.32549	Double Read
					VISIT 8	12OCT2017	8:24	9.867185	Double Read
					VISIT 11	24SEP2020	8:50	9.98905	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	2_3		Cranial Disc, not treated	Complete Disc	Baseline	08JUL2015	7:40	10.26653	Double Read
					VISIT 3A	28SEP2015	7:09	10.71595	Double Read
					VISIT 4	06NOV2015	8:22	10.7099	Double Read
					VISIT 6	14MAR2016	7:23	11.09235	Double Read
					VISIT 7	27SEP2016	7:00	10.146	Double Read
					VISIT 8	12OCT2017	8:24	11.51755	Double Read
					VISIT 11	24SEP2020	8:50	11.378	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	2_3		Caudal Disc		Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	2_3		Central Disc		Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	2_3		Caudal Disc		Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	2_3		Central Disc		Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
Normal lordotic LS	2_3		General		Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	Y	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	2_3		Caudal Disc		Baseline	08JUL2015	7:40	0	Double Read
					VISIT 3A	28SEP2015	7:09	0	Double Read
					VISIT 4	06NOV2015	8:22	0	Double Read
					VISIT 6	14MAR2016	7:23	0	Double Read
					VISIT 7	27SEP2016	7:00	0	Double Read
					VISIT 8	12OCT2017	8:24	0	Double Read
					VISIT 11	24SEP2020	8:50	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	2_3		Central Disc		Baseline	08JUL2015	7:40	0	Double Read
					VISIT 3A	28SEP2015	7:09	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	2_3		Central Disc		VISIT 4	06NOV2015	8:22	0	Double Read
					VISIT 6	14MAR2016	7:23	0	Double Read
					VISIT 7	27SEP2016	7:00	0	Double Read
					VISIT 8	12OCT2017	8:24	0	Double Read
					VISIT 11	24SEP2020	8:50	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		Baseline	08JUL2015	7:40	0	Double Read
					VISIT 3A	28SEP2015	7:09	0	Double Read
					VISIT 4	06NOV2015	8:22	0	Double Read
					VISIT 6	14MAR2016	7:23	0	Double Read
					VISIT 7	27SEP2016	7:00	0	Double Read
					VISIT 8	12OCT2017	8:24	0	Double Read
Protruding osteophyte (Caudal Disc)	2_3		Caudal Disc		VISIT 11	24SEP2020	8:50	0	Double Read
					Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	N	Double Read
Protruding osteophyte (Central Disc)	2_3		Central Disc		VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
					Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
					Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
Relevant scoliosis	2_3		General		Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	2_3		Caudal Disc		Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	2_3		Central Disc		Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	2_3		Cranial Disc, not treated		Baseline	08JUL2015	7:40	N	Double Read
					VISIT 3A	28SEP2015	7:09	N	Double Read
					VISIT 4	06NOV2015	8:22	N	Double Read
					VISIT 6	14MAR2016	7:23	N	Double Read
					VISIT 7	27SEP2016	7:00	N	Double Read
					VISIT 8	12OCT2017	8:24	N	Double Read
					VISIT 11	24SEP2020	8:50	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	2_3		Caudal Disc	Anulus Fibrosus	Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	2_3		Caudal Disc	Complete Disc	Baseline	08JUL2015	7:40	78.112	Double Read
					VISIT 3A	28SEP2015	7:09	83.58656	Double Read
					VISIT 4	06NOV2015	8:22	92.7144	Double Read
					VISIT 6	14MAR2016	7:23	80.56256	Double Read
					VISIT 7	27SEP2016	7:00	84.13216	Double Read
					VISIT 8	12OCT2017	8:24	88.04208	Double Read
					VISIT 11	24SEP2020	8:50	75.10672	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	2_3		Caudal Disc	Nucleus Pulposus	Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	2_3		Central Disc	Anulus Fibrosus	Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read
T2 (ms) (Central Disc, Complete Disc)	2_3		Central Disc	Complete Disc	Baseline	08JUL2015	7:40	75.39408	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	2_3		Central Disc	Complete Disc	VISIT 3A	28SEP2015	7:09	81.3584	Double Read
					VISIT 4	06NOV2015	8:22	83.39888	Double Read
					VISIT 6	14MAR2016	7:23	88.31168	Double Read
					VISIT 7	27SEP2016	7:00	81.50832	Double Read
					VISIT 8	12OCT2017	8:24	91.14992	Double Read
					VISIT 11	24SEP2020	8:50	84.1672	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	2_3		Central Disc	Nucleus Pulposus	Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	2_3		Cranial Disc, not treated	Anulus Fibrosus	Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	2_3		Cranial Disc, not treated	Complete Disc	VISIT 11	24SEP2020	8:50		Double Read
					Baseline	08JUL2015	7:40	82.68816	Double Read
					VISIT 3A	28SEP2015	7:09	81.47392	Double Read
					VISIT 4	06NOV2015	8:22	83.53424	Double Read
					VISIT 6	14MAR2016	7:23	85.86032	Double Read
					VISIT 7	27SEP2016	7:00	84.16544	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	2_3		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	12OCT2017	8:24	83.05728	Double Read
					VISIT 11	24SEP2020	8:50	79.888	Double Read
					Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	2_3		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	2_3		Caudal Disc		Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	2_3		Central Disc		Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	2_3		Cranial Disc, not treated		Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	2_3		Caudal Disc		Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	2_3		Central Disc		Baseline	08JUL2015	7:40	higher	Double Read
					VISIT 3A	28SEP2015	7:09	equal	Double Read
					VISIT 4	06NOV2015	8:22	equal	Double Read
					VISIT 6	14MAR2016	7:23	equal	Double Read
					VISIT 7	27SEP2016	7:00	equal	Double Read
					VISIT 8	12OCT2017	8:24	equal	Double Read
					VISIT 11	24SEP2020	8:50	equal	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	2_3		Cranial Disc, not treated		Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	2_3		Caudal Disc		Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	2_3		Caudal Disc		VISIT 11	24SEP2020	8:50		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	2_3		Central Disc		Baseline	08JUL2015	7:40	lower	Double Read
					VISIT 3A	28SEP2015	7:09	lower	Double Read
					VISIT 4	06NOV2015	8:22	lower	Double Read
					VISIT 6	14MAR2016	7:23	lower	Double Read
					VISIT 7	27SEP2016	7:00	lower	Double Read
					VISIT 8	12OCT2017	8:24	lower	Double Read
					VISIT 11	24SEP2020	8:50	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	2_3		Cranial Disc, not treated		Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	2_3		Caudal Disc		Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	2_3		Central Disc		Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	2_3		Central Disc		VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	2_3		Cranial Disc, not treated		Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	2_3		Caudal Disc	Anulus Fibrosus	Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	2_3		Caudal Disc	Complete Disc	Baseline	08JUL2015	7:40	8.1507253269	Double Read
					VISIT 3A	28SEP2015	7:09	6.3598505180	Double Read
					VISIT 4	06NOV2015	8:22	9.9654628843	Double Read
					VISIT 6	14MAR2016	7:23	6.4577339901	Double Read
					VISIT 7	27SEP2016	7:00	7.9260268387	Double Read
					VISIT 8	12OCT2017	8:24	8.1947409546	Double Read
					VISIT 11	24SEP2020	8:50	4.2013453371	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	2_3		Caudal Disc	Nucleus Pulposus	Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	2_3		Central Disc	Anulus Fibrosus	Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read
T2_error (ms) (Central Disc, Complete Disc)	2_3		Central Disc	Complete Disc	Baseline	08JUL2015	7:40	6.2129709529	Double Read
					VISIT 3A	28SEP2015	7:09	8.3599728214	Double Read
					VISIT 4	06NOV2015	8:22	8.2384915916	Double Read
					VISIT 6	14MAR2016	7:23	10.475060302	Double Read
					VISIT 7	27SEP2016	7:00	5.4640122303	Double Read
					VISIT 8	12OCT2017	8:24	8.3517309325	Double Read
					VISIT 11	24SEP2020	8:50	4.1766400543	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	2_3		Central Disc	Nucleus Pulposus	Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	2_3		Central Disc	Nucleus Pulposus	VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	2_3		Cranial Disc, not treated	Anulus Fibrosus	Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	2_3		Cranial Disc, not treated	Complete Disc	Baseline	08JUL2015	7:40	7.8455104467	Double Read
					VISIT 3A	28SEP2015	7:09	5.7074910820	Double Read
					VISIT 4	06NOV2015	8:22	12.456830304	Double Read
					VISIT 6	14MAR2016	7:23	11.072383217	Double Read
					VISIT 7	27SEP2016	7:00	13.973888228	Double Read
					VISIT 8	12OCT2017	8:24	9.8522167487	Double Read
					VISIT 11	24SEP2020	8:50	11.647942925	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	2_3		Cranial Disc, not treated	Nucleus Pulposus	Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	2_3		Caudal Disc	Anulus Fibrosus	Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	2_3		Caudal Disc	Complete Disc	Baseline	08JUL2015	7:40	17056.0	Double Read
					VISIT 3A	28SEP2015	7:09	16630.0	Double Read
					VISIT 4	06NOV2015	8:22	17371.0	Double Read
					VISIT 6	14MAR2016	7:23	19018.0	Double Read
					VISIT 7	27SEP2016	7:00	18061.5	Double Read
					VISIT 8	12OCT2017	8:24	15693.0	Double Read
					VISIT 11	24SEP2020	8:50	18850.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	2_3		Caudal Disc	Nucleus Pulposus	Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	2_3		Central Disc	Anulus Fibrosus	Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	2_3		Central Disc	Complete Disc	Baseline	08JUL2015	7:40	17100.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	2_3		Central Disc	Complete Disc	VISIT 3A	28SEP2015	7:09	17615.5	Double Read
					VISIT 4	06NOV2015	8:22	18812.5	Double Read
					VISIT 6	14MAR2016	7:23	19494.0	Double Read
					VISIT 7	27SEP2016	7:00	19944.0	Double Read
					VISIT 8	12OCT2017	8:24	17371.5	Double Read
					VISIT 11	24SEP2020	8:50	19273.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	2_3		Central Disc	Nucleus Pulposus	Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	2_3		Cranial Disc, not treated	Anulus Fibrosus	Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read
					VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	2_3		Cranial Disc, not treated	Complete Disc	Baseline	08JUL2015	7:40	15104.0	Double Read
					VISIT 3A	28SEP2015	7:09	15405.0	Double Read
					VISIT 4	06NOV2015	8:22	17479.0	Double Read
					VISIT 6	14MAR2016	7:23	17346.0	Double Read
					VISIT 7	27SEP2016	7:00	16151.0	Double Read
					VISIT 8	12OCT2017	8:24	17147.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	2_3		Cranial Disc, not treated	Nucleus Pulposus	Baseline	08JUL2015	7:40		Double Read
					VISIT 3A	28SEP2015	7:09		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0806 Age=54 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	2_3		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	06NOV2015	8:22		Double Read
					VISIT 6	14MAR2016	7:23		Double Read
					VISIT 7	27SEP2016	7:00		Double Read
					VISIT 8	12OCT2017	8:24		Double Read
					VISIT 11	24SEP2020	8:50		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0807 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	18NOV2015	7:40	2	Double Read
					VISIT 3A	01FEB2016	7:17	2	Double Read
					VISIT 4	11MAR2016	14:17	2	Double Read
					VISIT 6	28JUL2016	7:23	2	Double Read
					VISIT 7	06FEB2017	7:27	2	Double Read
					VISIT 8	19FEB2018	9:21	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	18NOV2015	7:40	4	Double Read
					VISIT 3A	01FEB2016	7:17	4	Double Read
					VISIT 4	11MAR2016	14:17	4	Double Read
					VISIT 6	28JUL2016	7:23	4	Double Read
					VISIT 7	06FEB2017	7:27	4	Double Read
					VISIT 8	19FEB2018	9:21	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	18NOV2015	7:40	3	Double Read
					VISIT 3A	01FEB2016	7:17	3	Double Read
					VISIT 4	11MAR2016	14:17	3	Double Read
					VISIT 6	28JUL2016	7:23	3	Double Read
					VISIT 7	06FEB2017	7:27	3	Double Read
					VISIT 8	19FEB2018	9:21	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read
					VISIT 8	19FEB2018	9:21	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0807 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 8	19FEB2018	9:21	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read
					VISIT 8	19FEB2018	9:21	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read
					VISIT 8	19FEB2018	9:21	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	18NOV2015	7:40	Y	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	Y	Double Read
					VISIT 6	28JUL2016	7:23	Y	Double Read
					VISIT 7	06FEB2017	7:27	Y	Double Read
					VISIT 8	19FEB2018	9:21	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read
					VISIT 8	19FEB2018	9:21	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0807 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	4_5		General		VISIT 8	19FEB2018	9:21	N	Double Read
Fracture	4_5		General		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read
					VISIT 8	19FEB2018	9:21	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	18NOV2015	7:40	13.62	Double Read
					VISIT 3A	01FEB2016	7:17	13.205	Double Read
					VISIT 4	11MAR2016	14:17	14.795	Double Read
					VISIT 6	28JUL2016	7:23	13.905	Double Read
					VISIT 7	06FEB2017	7:27	14.695	Double Read
					VISIT 8	19FEB2018	9:21	13.92	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	18NOV2015	7:40	11.82	Double Read
					VISIT 3A	01FEB2016	7:17	12.12	Double Read
					VISIT 4	11MAR2016	14:17	13.095	Double Read
					VISIT 6	28JUL2016	7:23	12.115	Double Read
					VISIT 7	06FEB2017	7:27	13.14	Double Read
					VISIT 8	19FEB2018	9:21	12.305	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	18NOV2015	7:40	12.825	Double Read
					VISIT 3A	01FEB2016	7:17	12.525	Double Read
					VISIT 4	11MAR2016	14:17	13.735	Double Read
					VISIT 6	28JUL2016	7:23	13.735	Double Read
					VISIT 7	06FEB2017	7:27	13.175	Double Read
					VISIT 8	19FEB2018	9:21	12.42	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	18NOV2015	7:40	10.28616	Double Read
					VISIT 3A	01FEB2016	7:17	10.430995	Double Read
					VISIT 4	11MAR2016	14:17	9.990955	Double Read
					VISIT 6	28JUL2016	7:23	10.10545	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0807 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	VISIT 7	06FEB2017	7:27	10.051265	Double Read
					VISIT 8	19FEB2018	9:21	10.63512	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	18NOV2015	7:40	9.63833	Double Read
					VISIT 3A	01FEB2016	7:17	10.18735	Double Read
					VISIT 4	11MAR2016	14:17	10.212685	Double Read
					VISIT 6	28JUL2016	7:23	10.07435	Double Read
					VISIT 7	06FEB2017	7:27	9.909075	Double Read
					VISIT 8	19FEB2018	9:21	9.650785	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	18NOV2015	7:40	10.36841	Double Read
					VISIT 3A	01FEB2016	7:17	11.457	Double Read
					VISIT 4	11MAR2016	14:17	10.45965	Double Read
					VISIT 6	28JUL2016	7:23	9.97048	Double Read
					VISIT 7	06FEB2017	7:27	10.4754	Double Read
					VISIT 8	19FEB2018	9:21	9.61557	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read
					VISIT 8	19FEB2018	9:21	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read
					VISIT 8	19FEB2018	9:21	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0807 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read
					VISIT 8	19FEB2018	9:21	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read
					VISIT 8	19FEB2018	9:21	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read
					VISIT 8	19FEB2018	9:21	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read
					VISIT 8	19FEB2018	9:21	N	Double Read
Normal lordotic LS	4_5		General		Baseline	18NOV2015	7:40	Y	Double Read
					VISIT 3A	01FEB2016	7:17	Y	Double Read
					VISIT 4	11MAR2016	14:17	Y	Double Read
					VISIT 6	28JUL2016	7:23	Y	Double Read
					VISIT 7	06FEB2017	7:27	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0807 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	4_5		General		VISIT 8	19FEB2018	9:21	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	18NOV2015	7:40	0	Double Read
					VISIT 3A	01FEB2016	7:17	0	Double Read
					VISIT 4	11MAR2016	14:17	0	Double Read
					VISIT 6	28JUL2016	7:23	0	Double Read
					VISIT 7	06FEB2017	7:27	0	Double Read
					VISIT 8	19FEB2018	9:21	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	18NOV2015	7:40	0	Double Read
					VISIT 3A	01FEB2016	7:17	0	Double Read
					VISIT 4	11MAR2016	14:17	2	Double Read
					VISIT 6	28JUL2016	7:23	0	Double Read
					VISIT 7	06FEB2017	7:27	0	Double Read
					VISIT 8	19FEB2018	9:21	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	18NOV2015	7:40	0	Double Read
					VISIT 3A	01FEB2016	7:17	0	Double Read
					VISIT 4	11MAR2016	14:17	2	Double Read
					VISIT 6	28JUL2016	7:23	0	Double Read
					VISIT 7	06FEB2017	7:27	0	Double Read
					VISIT 8	19FEB2018	9:21	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read
					VISIT 8	19FEB2018	9:21	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0807 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	19FEB2018	9:21	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read
					VISIT 8	19FEB2018	9:21	N	Double Read
Relevant scoliosis	4_5		General		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read
					VISIT 8	19FEB2018	9:21	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read
					VISIT 8	19FEB2018	9:21	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read
					VISIT 7	06FEB2017	7:27	N	Double Read
					VISIT 8	19FEB2018	9:21	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	18NOV2015	7:40	N	Double Read
					VISIT 3A	01FEB2016	7:17	N	Double Read
					VISIT 4	11MAR2016	14:17	N	Double Read
					VISIT 6	28JUL2016	7:23	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0807 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	06FEB2017	7:27	N	Double Read
					VISIT 8	19FEB2018	9:21	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	18NOV2015	7:40	90.07744	Double Read
					VISIT 3A	01FEB2016	7:17	91.57472	Double Read
					VISIT 4	11MAR2016	14:17	93.23424	Double Read
					VISIT 6	28JUL2016	7:23	92.75312	Double Read
					VISIT 7	06FEB2017	7:27	88.06288	Double Read
					VISIT 8	19FEB2018	9:21	85.70912	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	18NOV2015	7:40	82.1456	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0807 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	01FEB2016	7:17	82.09024	Double Read
					VISIT 4	11MAR2016	14:17	82.45712	Double Read
					VISIT 6	28JUL2016	7:23	87.13072	Double Read
					VISIT 7	06FEB2017	7:27	83.88576	Double Read
					VISIT 8	19FEB2018	9:21	81.14032	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	18NOV2015	7:40	82.49264	Double Read
					VISIT 3A	01FEB2016	7:17	84.75344	Double Read
					VISIT 4	11MAR2016	14:17	79.33184	Double Read
					VISIT 6	28JUL2016	7:23	83.56336	Double Read
					VISIT 7	06FEB2017	7:27	80.3064	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	19FEB2018	9:21	81.16144	Double Read
					Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0807 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0807 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	18NOV2015	7:40	lower	Double Read
					VISIT 3A	01FEB2016	7:17	lower	Double Read
					VISIT 4	11MAR2016	14:17	lower	Double Read
					VISIT 6	28JUL2016	7:23	lower	Double Read
					VISIT 7	06FEB2017	7:27	lower	Double Read
					VISIT 8	19FEB2018	9:21	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	18NOV2015	7:40	lower	Double Read
					VISIT 3A	01FEB2016	7:17	lower	Double Read
					VISIT 4	11MAR2016	14:17	lower	Double Read
					VISIT 6	28JUL2016	7:23	lower	Double Read
					VISIT 7	06FEB2017	7:27	lower	Double Read
					VISIT 8	19FEB2018	9:21	equal	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0807 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0807 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	18NOV2015	7:40	4.76231017496	Double Read
					VISIT 3A	01FEB2016	7:17	3.1904331578	Double Read
					VISIT 4	11MAR2016	14:17	8.81320197042	Double Read
					VISIT 6	28JUL2016	7:23	14.0092339052	Double Read
					VISIT 7	06FEB2017	7:27	8.82656701205	Double Read
					VISIT 8	19FEB2018	9:21	9.32239850518	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	18NOV2015	7:40	8.83302191269	Double Read
					VISIT 3A	01FEB2016	7:17	6.26444029217	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0807 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 4	11MAR2016	14:17	3.34505180907	Double Read
					VISIT 6	28JUL2016	7:23	6.1465330389	Double Read
					VISIT 7	06FEB2017	7:27	6.50963818583	Double Read
					VISIT 8	19FEB2018	9:21	7.07357907253	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	18NOV2015	7:40	10.5121250212	Double Read
					VISIT 3A	01FEB2016	7:17	6.01810090029	Double Read
					VISIT 4	11MAR2016	14:17	3.51763546798	Double Read
					VISIT 6	28JUL2016	7:23	7.06641753015	Double Read
					VISIT 7	06FEB2017	7:27	7.16447766265	Double Read
					VISIT 8	19FEB2018	9:21	10.3800169866	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0807 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	18NOV2015	7:40	8712.0	Double Read
					VISIT 3A	01FEB2016	7:17	8918.5	Double Read
					VISIT 4	11MAR2016	14:17	9311.5	Double Read
					VISIT 6	28JUL2016	7:23	8820.0	Double Read
					VISIT 7	06FEB2017	7:27	9328.5	Double Read
					VISIT 8	19FEB2018	9:21	8816.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0807 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	VISIT 8	19FEB2018	9:21		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	18NOV2015	7:40	9118.5	Double Read
					VISIT 3A	01FEB2016	7:17	9873.0	Double Read
					VISIT 4	11MAR2016	14:17	9828.5	Double Read
					VISIT 6	28JUL2016	7:23	9848.0	Double Read
					VISIT 7	06FEB2017	7:27	9963.0	Double Read
					VISIT 8	19FEB2018	9:21	9381.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read
					VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	18NOV2015	7:40	11692.0	Double Read
					VISIT 3A	01FEB2016	7:17	12629.5	Double Read
					VISIT 4	11MAR2016	14:17	12556.5	Double Read
					VISIT 6	28JUL2016	7:23	11788.0	Double Read
					VISIT 7	06FEB2017	7:27	11910.0	Double Read
					VISIT 8	19FEB2018	9:21	11420.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	18NOV2015	7:40		Double Read
					VISIT 3A	01FEB2016	7:17		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0807 Age=48 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	11MAR2016	14:17		Double Read
					VISIT 6	28JUL2016	7:23		Double Read
					VISIT 7	06FEB2017	7:27		Double Read
					VISIT 8	19FEB2018	9:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0808 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	3_4		Caudal Disc		Baseline	03DEC2015	7:13	3	Double Read
					VISIT 4	07JAN2016	7:20	4	Double Read
					VISIT 6	03JUN2016	7:47	4	Double Read
					VISIT 7	28NOV2016	7:21	3	Double Read
					VISIT 8	13NOV2017	8:22	4	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	3_4		Central Disc		Baseline	03DEC2015	7:13	2	Double Read
					VISIT 4	07JAN2016	7:20	3	Double Read
					VISIT 6	03JUN2016	7:47	4	Double Read
					VISIT 7	28NOV2016	7:21	3	Double Read
					VISIT 8	13NOV2017	8:22	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	03DEC2015	7:13	2	Double Read
					VISIT 4	07JAN2016	7:20	2	Double Read
					VISIT 6	03JUN2016	7:47	3	Double Read
					VISIT 7	28NOV2016	7:21	2	Double Read
					VISIT 8	13NOV2017	8:22	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	3_4		Caudal Disc		Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
					VISIT 8	13NOV2017	8:22	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	3_4		Central Disc		Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
					VISIT 8	13NOV2017	8:22	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0808 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
					VISIT 8	13NOV2017	8:22	N	Double Read
Dorsal disc extrusion (Caudal Disc)	3_4		Caudal Disc		Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
					VISIT 8	13NOV2017	8:22	N	Double Read
Dorsal disc extrusion (Central Disc)	3_4		Central Disc		Baseline	03DEC2015	7:13	Y	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	Y	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
					VISIT 8	13NOV2017	8:22	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	Y	Double Read
Extradiscal fluid collection	3_4		General		VISIT 8	13NOV2017	8:22	Y	Double Read
					Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
Fracture	3_4		General		VISIT 8	13NOV2017	8:22	N	Double Read
					Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	03DEC2015	7:13	14.235	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0808 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	VISIT 4	07JAN2016	7:20	14.655	Double Read
					VISIT 6	03JUN2016	7:47	14.58	Double Read
					VISIT 7	28NOV2016	7:21	15.045	Double Read
					VISIT 8	13NOV2017	8:22	15.775	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	03DEC2015	7:13	15.375	Double Read
					VISIT 4	07JAN2016	7:20	15.275	Double Read
					VISIT 6	03JUN2016	7:47	15.675	Double Read
					VISIT 7	28NOV2016	7:21	15.305	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	VISIT 8	13NOV2017	8:22	14.49	Double Read
					Baseline	03DEC2015	7:13	13.67	Double Read
					VISIT 4	07JAN2016	7:20	13.59	Double Read
					VISIT 6	03JUN2016	7:47	14.135	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	VISIT 7	28NOV2016	7:21	13.23	Double Read
					VISIT 8	13NOV2017	8:22	13.96	Double Read
					Baseline	03DEC2015	7:13	10.52885	Double Read
					VISIT 4	07JAN2016	7:20	9.3201	Double Read
Height manual (mm) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	VISIT 6	03JUN2016	7:47	9.45375	Double Read
					VISIT 7	28NOV2016	7:21	9.386445	Double Read
					VISIT 8	13NOV2017	8:22	9.287595	Double Read
					Baseline	03DEC2015	7:13	11.7274	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	VISIT 4	07JAN2016	7:20	10.57235	Double Read
					VISIT 6	03JUN2016	7:47	11.0117	Double Read
					VISIT 7	28NOV2016	7:21	10.522655	Double Read
					VISIT 8	13NOV2017	8:22	11.6343	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	03DEC2015	7:13	12.1853	Double Read
					VISIT 4	07JAN2016	7:20	11.1488	Double Read
					VISIT 6	03JUN2016	7:47	11.302605	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0808 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	VISIT 7	28NOV2016	7:21	12.1188	Double Read
					VISIT 8	13NOV2017	8:22	11.46995	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	3_4		Caudal Disc		Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
					VISIT 8	13NOV2017	8:22	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	3_4		Central Disc		Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
					VISIT 8	13NOV2017	8:22	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
					VISIT 8	13NOV2017	8:22	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	3_4		Caudal Disc		Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
					VISIT 8	13NOV2017	8:22	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	3_4		Central Disc		Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0808 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	3_4		Central Disc		VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
					VISIT 8	13NOV2017	8:22	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
					VISIT 8	13NOV2017	8:22	N	Double Read
Normal lordotic LS	3_4		General		Baseline	03DEC2015	7:13	Y	Double Read
					VISIT 4	07JAN2016	7:20	Y	Double Read
					VISIT 6	03JUN2016	7:47	Y	Double Read
					VISIT 7	28NOV2016	7:21	Y	Double Read
					VISIT 8	13NOV2017	8:22	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	3_4		Caudal Disc		Baseline	03DEC2015	7:13	0	Double Read
					VISIT 4	07JAN2016	7:20	0	Double Read
					VISIT 6	03JUN2016	7:47	0	Double Read
					VISIT 7	28NOV2016	7:21	0	Double Read
					VISIT 8	13NOV2017	8:22	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	3_4		Central Disc		Baseline	03DEC2015	7:13	0	Double Read
					VISIT 4	07JAN2016	7:20	0	Double Read
					VISIT 6	03JUN2016	7:47	0	Double Read
					VISIT 7	28NOV2016	7:21	0	Double Read
					VISIT 8	13NOV2017	8:22	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	03DEC2015	7:13	0	Double Read
					VISIT 4	07JAN2016	7:20	0	Double Read
					VISIT 6	03JUN2016	7:47	0	Double Read
					VISIT 7	28NOV2016	7:21	0	Double Read
					VISIT 8	13NOV2017	8:22	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0808 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Caudal Disc)	3_4		Caudal Disc		Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
					VISIT 8	13NOV2017	8:22	N	Double Read
Protruding osteophyte (Central Disc)	3_4		Central Disc		Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
					VISIT 8	13NOV2017	8:22	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
					VISIT 8	13NOV2017	8:22	N	Double Read
Relevant scoliosis	3_4		General		Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
					VISIT 8	13NOV2017	8:22	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	3_4		Caudal Disc		Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
					VISIT 8	13NOV2017	8:22	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	3_4		Central Disc		Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
					VISIT 8	13NOV2017	8:22	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0808 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	03DEC2015	7:13	N	Double Read
					VISIT 4	07JAN2016	7:20	N	Double Read
					VISIT 6	03JUN2016	7:47	N	Double Read
					VISIT 7	28NOV2016	7:21	N	Double Read
					VISIT 8	13NOV2017	8:22	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	03DEC2015	7:13	79.92624	Double Read
					VISIT 4	07JAN2016	7:20	85.84576	Double Read
					VISIT 6	03JUN2016	7:47	95.55312	Double Read
					VISIT 7	28NOV2016	7:21	85.76064	Double Read
					VISIT 8	13NOV2017	8:22	88.43984	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2 (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	03DEC2015	7:13	84.51312	Double Read
					VISIT 4	07JAN2016	7:20	93.07808	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0808 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	VISIT 6	03JUN2016	7:47	96.23312	Double Read
					VISIT 7	28NOV2016	7:21	78.49488	Double Read
					VISIT 8	13NOV2017	8:22	89.09664	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	03DEC2015	7:13	80.63392	Double Read
					VISIT 4	07JAN2016	7:20	86.20976	Double Read
					VISIT 6	03JUN2016	7:47	95.45072	Double Read
					VISIT 7	28NOV2016	7:21	85.53216	Double Read
					VISIT 8	13NOV2017	8:22	87.19184	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	3_4		Caudal Disc		Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0808 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	3_4		Caudal Disc		VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	3_4		Central Disc		Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	3_4		Caudal Disc		Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	3_4		Central Disc		Baseline	03DEC2015	7:13	higher	Double Read
					VISIT 4	07JAN2016	7:20	equal	Double Read
					VISIT 6	03JUN2016	7:47	equal	Double Read
					VISIT 7	28NOV2016	7:21	equal	Double Read
					VISIT 8	13NOV2017	8:22	equal	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0808 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	3_4		Caudal Disc		Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	3_4		Central Disc		Baseline	03DEC2015	7:13	lower	Double Read
					VISIT 4	07JAN2016	7:20	lower	Double Read
					VISIT 6	03JUN2016	7:47	lower	Double Read
					VISIT 7	28NOV2016	7:21	lower	Double Read
					VISIT 8	13NOV2017	8:22	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	3_4		Caudal Disc		Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0808 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	3_4		Central Disc		Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	03DEC2015	7:13	7.32445048412	Double Read
					VISIT 4	07JAN2016	7:20	7.617829115	Double Read
					VISIT 6	03JUN2016	7:47	10.8714115848	Double Read
					VISIT 7	28NOV2016	7:21	5.75328010871	Double Read
					VISIT 8	13NOV2017	8:22	7.51330049261	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0808 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2_error (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	03DEC2015	7:13	5.1639205028	Double Read
					VISIT 4	07JAN2016	7:20	6.0698692033	Double Read
					VISIT 6	03JUN2016	7:47	6.9797995583	Double Read
					VISIT 7	28NOV2016	7:21	6.9483200271	Double Read
					VISIT 8	13NOV2017	8:22	7.7458807542	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	03DEC2015	7:13	8.6065364362	Double Read
					VISIT 4	07JAN2016	7:20	9.4671649397	Double Read
					VISIT 6	03JUN2016	7:47	12.716242568	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0808 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	VISIT 7	28NOV2016	7:21	5.14474605062	Double Read
					VISIT 8	13NOV2017	8:22	8.84919993206	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	03DEC2015	7:13	16482.5	Double Read
					VISIT 4	07JAN2016	7:20	16065.5	Double Read
					VISIT 6	03JUN2016	7:47	17392.5	Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22	17465.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=08/0808 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	VISIT 8	13NOV2017	8:22		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	03DEC2015	7:13	16414.5	Double Read
					VISIT 4	07JAN2016	7:20	17342.5	Double Read
					VISIT 6	03JUN2016	7:47	18662.5	Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22	18489.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	03DEC2015	7:13	16834.0	Double Read
					VISIT 4	07JAN2016	7:20	16379.0	Double Read
					VISIT 6	03JUN2016	7:47	17192.5	Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22	17206.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	03DEC2015	7:13		Double Read
					VISIT 4	07JAN2016	7:20		Double Read
					VISIT 6	03JUN2016	7:47		Double Read
					VISIT 7	28NOV2016	7:21		Double Read
					VISIT 8	13NOV2017	8:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0901 Age=48 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirschmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
Disc degeneration grading (Pfirschmann) (Central Disc)	5_S		Central Disc		Baseline	29OCT2014	16:10	3	Double Read
					VISIT 4	08DEC2014	10:53	2	Double Read
					VISIT 6	05MAY2015	13:27	3	Double Read
					VISIT 7	03NOV2015	13:42	3	Double Read
					VISIT 8	22NOV2016	8:03	3	Double Read
					VISIT 11	28OCT2019	14:12	3	Double Read
Disc degeneration grading (Pfirschmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	29OCT2014	16:10	2	Double Read
					VISIT 4	08DEC2014	10:53	2	Double Read
					VISIT 6	05MAY2015	13:27	2	Double Read
					VISIT 7	03NOV2015	13:42	2	Double Read
					VISIT 8	22NOV2016	8:03	3	Double Read
					VISIT 11	28OCT2019	14:12	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	29OCT2014	16:10	N	Double Read
					VISIT 4	08DEC2014	10:53	N	Double Read
					VISIT 6	05MAY2015	13:27	N	Double Read
					VISIT 7	03NOV2015	13:42	N	Double Read
					VISIT 8	22NOV2016	8:03	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0901 Age=48 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 11	28OCT2019	14:12	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	29OCT2014	16:10	N	Double Read
					VISIT 4	08DEC2014	10:53	N	Double Read
					VISIT 6	05MAY2015	13:27	N	Double Read
					VISIT 7	03NOV2015	13:42	N	Double Read
					VISIT 8	22NOV2016	8:03	N	Double Read
					VISIT 11	28OCT2019	14:12	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	29OCT2014	16:10	N	Double Read
					VISIT 4	08DEC2014	10:53	Y	Double Read
					VISIT 6	05MAY2015	13:27	Y	Double Read
					VISIT 7	03NOV2015	13:42	N	Double Read
					VISIT 8	22NOV2016	8:03	N	Double Read
					VISIT 11	28OCT2019	14:12	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	29OCT2014	16:10	N	Double Read
					VISIT 4	08DEC2014	10:53	N	Double Read
					VISIT 6	05MAY2015	13:27	N	Double Read
					VISIT 7	03NOV2015	13:42	N	Double Read
					VISIT 8	22NOV2016	8:03	N	Double Read
					VISIT 11	28OCT2019	14:12	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	29OCT2014	16:10	N	Double Read
					VISIT 4	08DEC2014	10:53	N	Double Read
					VISIT 6	05MAY2015	13:27	N	Double Read
					VISIT 7	03NOV2015	13:42	N	Double Read
					VISIT 8	22NOV2016	8:03	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0901 Age=48 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 11	28OCT2019	14:12	N	Double Read
Fracture	5_S		General		Baseline	29OCT2014	16:10	N	Double Read
					VISIT 4	08DEC2014	10:53	N	Double Read
					VISIT 6	05MAY2015	13:27	N	Double Read
					VISIT 7	03NOV2015	13:42	N	Double Read
					VISIT 8	22NOV2016	8:03	N	Double Read
					VISIT 11	28OCT2019	14:12	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	29OCT2014	16:10	14.29	Double Read
					VISIT 4	08DEC2014	10:53	14.605	Double Read
					VISIT 6	05MAY2015	13:27	14.32	Double Read
					VISIT 7	03NOV2015	13:42	14.41	Double Read
					VISIT 8	22NOV2016	8:03	14.895	Double Read
					VISIT 11	28OCT2019	14:12	14.46	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	29OCT2014	16:10	14.1	Double Read
					VISIT 4	08DEC2014	10:53	14.76	Double Read
					VISIT 6	05MAY2015	13:27	15.22	Double Read
					VISIT 7	03NOV2015	13:42	14.47	Double Read
					VISIT 8	22NOV2016	8:03	15.095	Double Read
					VISIT 11	28OCT2019	14:12	15.515	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0901 Age=48 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	29OCT2014	16:10	11.92795	Double Read
					VISIT 4	08DEC2014	10:53	11.86455	Double Read
					VISIT 6	05MAY2015	13:27	10.3314	Double Read
					VISIT 7	03NOV2015	13:42	9.54278	Double Read
					VISIT 8	22NOV2016	8:03	11.01495	Double Read
					VISIT 11	28OCT2019	14:12	11.20155	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	29OCT2014	16:10	12.678	Double Read
					VISIT 4	08DEC2014	10:53	12.33855	Double Read
					VISIT 6	05MAY2015	13:27	12.2708	Double Read
					VISIT 7	03NOV2015	13:42	11.64965	Double Read
					VISIT 8	22NOV2016	8:03	12.49935	Double Read
					VISIT 11	28OCT2019	14:12	12.6558	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	29OCT2014	16:10	N	Double Read
					VISIT 4	08DEC2014	10:53	N	Double Read
					VISIT 6	05MAY2015	13:27	N	Double Read
					VISIT 7	03NOV2015	13:42	N	Double Read
					VISIT 8	22NOV2016	8:03	N	Double Read
					VISIT 11	28OCT2019	14:12	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0901 Age=48 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	29OCT2014	16:10	N	Double Read
					VISIT 4	08DEC2014	10:53	N	Double Read
					VISIT 6	05MAY2015	13:27	N	Double Read
					VISIT 7	03NOV2015	13:42	N	Double Read
					VISIT 8	22NOV2016	8:03	N	Double Read
					VISIT 11	28OCT2019	14:12	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	29OCT2014	16:10	N	Double Read
					VISIT 4	08DEC2014	10:53	N	Double Read
					VISIT 6	05MAY2015	13:27	N	Double Read
					VISIT 7	03NOV2015	13:42	N	Double Read
					VISIT 8	22NOV2016	8:03	N	Double Read
					VISIT 11	28OCT2019	14:12	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	29OCT2014	16:10	N	Double Read
					VISIT 4	08DEC2014	10:53	N	Double Read
					VISIT 6	05MAY2015	13:27	N	Double Read
					VISIT 7	03NOV2015	13:42	N	Double Read
					VISIT 8	22NOV2016	8:03	N	Double Read
					VISIT 11	28OCT2019	14:12	N	Double Read
Normal lordotic LS	5_S		General		Baseline	29OCT2014	16:10	Y	Double Read
					VISIT 4	08DEC2014	10:53	Y	Double Read
					VISIT 6	05MAY2015	13:27	Y	Double Read
					VISIT 7	03NOV2015	13:42	Y	Double Read
					VISIT 8	22NOV2016	8:03	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0901 Age=48 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	5_S		General		VISIT 11	28OCT2019	14:12	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	29OCT2014	16:10	0	Double Read
					VISIT 4	08DEC2014	10:53	0	Double Read
					VISIT 6	05MAY2015	13:27	0	Double Read
					VISIT 7	03NOV2015	13:42	0	Double Read
					VISIT 8	22NOV2016	8:03	0	Double Read
					VISIT 11	28OCT2019	14:12	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	29OCT2014	16:10	0	Double Read
					VISIT 4	08DEC2014	10:53	0	Double Read
					VISIT 6	05MAY2015	13:27	0	Double Read
					VISIT 7	03NOV2015	13:42	0	Double Read
					VISIT 8	22NOV2016	8:03	0	Double Read
					VISIT 11	28OCT2019	14:12	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	29OCT2014	16:10	N	Double Read
					VISIT 4	08DEC2014	10:53	N	Double Read
					VISIT 6	05MAY2015	13:27	N	Double Read
					VISIT 7	03NOV2015	13:42	N	Double Read
					VISIT 8	22NOV2016	8:03	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0901 Age=48 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 11	28OCT2019	14:12	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	29OCT2014	16:10	N	Double Read
					VISIT 4	08DEC2014	10:53	N	Double Read
					VISIT 6	05MAY2015	13:27	N	Double Read
					VISIT 7	03NOV2015	13:42	N	Double Read
					VISIT 8	22NOV2016	8:03	N	Double Read
					VISIT 11	28OCT2019	14:12	N	Double Read
Relevant scoliosis	5_S		General		Baseline	29OCT2014	16:10	N	Double Read
					VISIT 4	08DEC2014	10:53	N	Double Read
					VISIT 6	05MAY2015	13:27	N	Double Read
					VISIT 7	03NOV2015	13:42	N	Double Read
					VISIT 8	22NOV2016	8:03	N	Double Read
					VISIT 11	28OCT2019	14:12	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	29OCT2014	16:10	N	Double Read
					VISIT 4	08DEC2014	10:53	N	Double Read
					VISIT 6	05MAY2015	13:27	N	Double Read
					VISIT 7	03NOV2015	13:42	N	Double Read
					VISIT 8	22NOV2016	8:03	N	Double Read
					VISIT 11	28OCT2019	14:12	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	29OCT2014	16:10	N	Double Read
					VISIT 4	08DEC2014	10:53	N	Double Read
					VISIT 6	05MAY2015	13:27	N	Double Read
					VISIT 7	03NOV2015	13:42	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0901 Age=48 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	22NOV2016	8:03	N	Double Read
					VISIT 11	28OCT2019	14:12	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	29OCT2014	16:10	60.73808	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0901 Age=48 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 4	08DEC2014	10:53	64.34416	Double Read
					VISIT 6	05MAY2015	13:27	67.03968	Double Read
					VISIT 7	03NOV2015	13:42	63.56368	Double Read
					VISIT 8	22NOV2016	8:03	65.9296	Double Read
					VISIT 11	28OCT2019	14:12	61.53712	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	29OCT2014	16:10	74.99824	Double Read
					VISIT 4	08DEC2014	10:53	73.04656	Double Read
					VISIT 6	05MAY2015	13:27	76.3496	Double Read
					VISIT 7	03NOV2015	13:42	74.7224	Double Read
					VISIT 8	22NOV2016	8:03	73.8328	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	28OCT2019	14:12	69.30144	Double Read
					Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0901 Age=48 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0901 Age=48 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	29OCT2014	16:10	lower	Double Read
					VISIT 4	08DEC2014	10:53	equal	Double Read
					VISIT 6	05MAY2015	13:27	lower	Double Read
					VISIT 7	03NOV2015	13:42	equal	Double Read
					VISIT 8	22NOV2016	8:03	equal	Double Read
					VISIT 11	28OCT2019	14:12	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0901 Age=48 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0901 Age=48 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	29OCT2014	16:10	7.8994326482	Double Read
					VISIT 4	08DEC2014	10:53	4.8380907083	Double Read
					VISIT 6	05MAY2015	13:27	7.4795107864	Double Read
					VISIT 7	03NOV2015	13:42	10.995542721	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0901 Age=48 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	22NOV2016	8:03	10.960815355	Double Read
					VISIT 11	28OCT2019	14:12	8.2022490232	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	29OCT2014	16:10	9.415722779	Double Read
					VISIT 4	08DEC2014	10:53	6.0739935451	Double Read
					VISIT 6	05MAY2015	13:27	11.492631221	Double Read
					VISIT 7	03NOV2015	13:42	6.9887684729	Double Read
					VISIT 8	22NOV2016	8:03	11.017013759	Double Read
					VISIT 11	28OCT2019	14:12	11.331938168	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0901 Age=48 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	29OCT2014	16:10	16677.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0901 Age=48 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 4	08DEC2014	10:53	16726.0	Double Read
					VISIT 6	05MAY2015	13:27	15503.0	Double Read
					VISIT 7	03NOV2015	13:42	16735.0	Double Read
					VISIT 8	22NOV2016	8:03	19524.0	Double Read
					VISIT 11	28OCT2019	14:12	15534.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	29OCT2014	16:10	18474.0	Double Read
					VISIT 4	08DEC2014	10:53	19260.0	Double Read
					VISIT 6	05MAY2015	13:27	19563.5	Double Read
					VISIT 7	03NOV2015	13:42	19772.5	Double Read
					VISIT 8	22NOV2016	8:03	21909.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	28OCT2019	14:12	20372.0	Double Read
					Baseline	29OCT2014	16:10		Double Read
					VISIT 4	08DEC2014	10:53		Double Read
					VISIT 6	05MAY2015	13:27		Double Read
					VISIT 7	03NOV2015	13:42		Double Read
					VISIT 8	22NOV2016	8:03		Double Read
					VISIT 11	28OCT2019	14:12		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0902 Age=51 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	12NOV2014	15:08		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	12NOV2014	15:08	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	12NOV2014	15:08	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	12NOV2014	15:08		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	12NOV2014	15:08	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	12NOV2014	15:08	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	12NOV2014	15:08		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	12NOV2014	15:08	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	12NOV2014	15:08	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	12NOV2014	15:08	N	Double Read
Fracture	5_S		General		Baseline	12NOV2014	15:08	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	12NOV2014	15:08		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	12NOV2014	15:08	9.62	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	12NOV2014	15:08	11.765	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0902 Age=51 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	12NOV2014	15:08		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	12NOV2014	15:08	6.95494	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	12NOV2014	15:08	8.79694	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	12NOV2014	15:08		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	12NOV2014	15:08	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	12NOV2014	15:08	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	12NOV2014	15:08		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	12NOV2014	15:08	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	12NOV2014	15:08	N	Double Read
Normal lordotic LS	5_S		General		Baseline	12NOV2014	15:08	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	12NOV2014	15:08		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	12NOV2014	15:08	3	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0902 Age=51 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	12NOV2014	15:08	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	12NOV2014	15:08		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	12NOV2014	15:08	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	12NOV2014	15:08	N	Double Read
Relevant scoliosis	5_S		General		Baseline	12NOV2014	15:08	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	12NOV2014	15:08		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	12NOV2014	15:08	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	12NOV2014	15:08	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	12NOV2014	15:08		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	12NOV2014	15:08		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	12NOV2014	15:08		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	12NOV2014	15:08		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	12NOV2014	15:08	63.86624	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	12NOV2014	15:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0902 Age=51 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	12NOV2014	15:08		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	12NOV2014	15:08	63.4176	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	12NOV2014	15:08		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	12NOV2014	15:08		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	12NOV2014	15:08		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	12NOV2014	15:08		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	12NOV2014	15:08		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	12NOV2014	15:08		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	12NOV2014	15:08		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	12NOV2014	15:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0902 Age=51 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	12NOV2014	15:08	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	12NOV2014	15:08		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	12NOV2014	15:08		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	12NOV2014	15:08		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	12NOV2014	15:08		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	12NOV2014	15:08		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	12NOV2014	15:08		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	12NOV2014	15:08		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	12NOV2014	15:08		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	12NOV2014	15:08	13.264093766	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	12NOV2014	15:08		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	12NOV2014	15:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0902 Age=51 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	12NOV2014	15:08	11.8339867505	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	12NOV2014	15:08		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	12NOV2014	15:08		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	12NOV2014	15:08		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	12NOV2014	15:08		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	12NOV2014	15:08		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	12NOV2014	15:08	7129.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	12NOV2014	15:08		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	12NOV2014	15:08		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	12NOV2014	15:08	11349.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	12NOV2014	15:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0903 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	3_4		Caudal Disc		Baseline	19NOV2014	13:47	3	Double Read
					VISIT 3A	11FEB2015	12:40	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	3_4		Central Disc		Baseline	19NOV2014	13:47	3	Double Read
					VISIT 3A	11FEB2015	12:40	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	19NOV2014	13:47	3	Double Read
					VISIT 3A	11FEB2015	12:40	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	3_4		Caudal Disc		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	3_4		Central Disc		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read
Dorsal disc extrusion (Caudal Disc)	3_4		Caudal Disc		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read
Dorsal disc extrusion (Central Disc)	3_4		Central Disc		Baseline	19NOV2014	13:47	Y	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read
Extradiscal fluid collection	3_4		General		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read
Fracture	3_4		General		Baseline	19NOV2014	13:47	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0903 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Fracture	3_4		General		VISIT 3A	11FEB2015	12:40	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	19NOV2014	13:47	17.3	Double Read
					VISIT 3A	11FEB2015	12:40	15.755	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	19NOV2014	13:47	15.07	Double Read
					VISIT 3A	11FEB2015	12:40	15.05	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	19NOV2014	13:47	14.805	Double Read
					VISIT 3A	11FEB2015	12:40	15.815	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	19NOV2014	13:47	10.0003	Double Read
					VISIT 3A	11FEB2015	12:40	9.88825	Double Read
Height manual (mm) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	19NOV2014	13:47	11.1604	Double Read
					VISIT 3A	11FEB2015	12:40	10.88525	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	19NOV2014	13:47	10.69325	Double Read
					VISIT 3A	11FEB2015	12:40	9.96948	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	3_4		Caudal Disc		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	3_4		Central Disc		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0903 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	3_4		Caudal Disc		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	3_4		Central Disc		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read
Normal lordotic LS	3_4		General		Baseline	19NOV2014	13:47	Y	Double Read
					VISIT 3A	11FEB2015	12:40	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	3_4		Caudal Disc		Baseline	19NOV2014	13:47	3	Double Read
					VISIT 3A	11FEB2015	12:40	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	3_4		Central Disc		Baseline	19NOV2014	13:47	0	Double Read
					VISIT 3A	11FEB2015	12:40	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	19NOV2014	13:47	0	Double Read
					VISIT 3A	11FEB2015	12:40	0	Double Read
Protruding osteophyte (Caudal Disc)	3_4		Caudal Disc		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read
Protruding osteophyte (Central Disc)	3_4		Central Disc		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0903 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read
Relevant scoliosis	3_4		General		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	3_4		Caudal Disc		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	3_4		Central Disc		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	3_4		Cranial Disc, not treated		Baseline	19NOV2014	13:47	N	Double Read
					VISIT 3A	11FEB2015	12:40	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	19NOV2014	13:47	67.20784	Double Read
					VISIT 3A	11FEB2015	12:40	71.36704	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2 (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	19NOV2014	13:47	67.1224	Double Read
					VISIT 3A	11FEB2015	12:40	63.57776	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0903 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	19NOV2014	13:47	66.86288	Double Read
					VISIT 3A	11FEB2015	12:40	68.59632	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	3_4		Caudal Disc		Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	3_4		Central Disc		Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	3_4		Caudal Disc		Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0903 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	3_4		Central Disc		Baseline	19NOV2014	13:47	equal	Double Read
					VISIT 3A	11FEB2015	12:40	equal	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	3_4		Caudal Disc		Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	3_4		Central Disc		Baseline	19NOV2014	13:47	equal	Double Read
					VISIT 3A	11FEB2015	12:40	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	3_4		Caudal Disc		Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	3_4		Central Disc		Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	3_4		Cranial Disc, not treated		Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0903 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	19NOV2014	13:47	10.5647698319	Double Read
					VISIT 3A	11FEB2015	12:40	6.85125191099	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2_error (ms) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	19NOV2014	13:47	8.10314251741	Double Read
					VISIT 3A	11FEB2015	12:40	9.52192288094	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	19NOV2014	13:47	8.79055546119	Double Read
					VISIT 3A	11FEB2015	12:40	5.81507049431	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0903 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	3_4		Caudal Disc	Anulus Fibrosus	Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	3_4		Caudal Disc	Complete Disc	Baseline	19NOV2014	13:47	21228.5	Double Read
					VISIT 3A	11FEB2015	12:40	20491.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	3_4		Caudal Disc	Nucleus Pulposus	Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	3_4		Central Disc	Anulus Fibrosus	Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	3_4		Central Disc	Complete Disc	Baseline	19NOV2014	13:47	22076.0	Double Read
					VISIT 3A	11FEB2015	12:40	22239.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	3_4		Central Disc	Nucleus Pulposus	Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	3_4		Cranial Disc, not treated	Anulus Fibrosus	Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	3_4		Cranial Disc, not treated	Complete Disc	Baseline	19NOV2014	13:47	21411.0	Double Read
					VISIT 3A	11FEB2015	12:40	21658.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	3_4		Cranial Disc, not treated	Nucleus Pulposus	Baseline	19NOV2014	13:47		Double Read
					VISIT 3A	11FEB2015	12:40		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	06FEB2015	15:28	2	Double Read
					VISIT 3A	20MAY2015	12:29	2	Double Read
					VISIT 4	08JUL2015	10:28	2	Double Read
					VISIT 6	17NOV2015	12:06	2	Double Read
					VISIT 7	23MAY2016	9:57	2	Double Read
					VISIT 8	24APR2017	9:04	2	Double Read
					VISIT 11	11MAY2020	8:33	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	06FEB2015	15:28	3	Double Read
					VISIT 3A	20MAY2015	12:29	3	Double Read
					VISIT 4	08JUL2015	10:28	3	Double Read
					VISIT 6	17NOV2015	12:06	3	Double Read
					VISIT 7	23MAY2016	9:57	3	Double Read
					VISIT 8	24APR2017	9:04	3	Double Read
					VISIT 11	11MAY2020	8:33	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	06FEB2015	15:28	2	Double Read
					VISIT 3A	20MAY2015	12:29	3	Double Read
					VISIT 4	08JUL2015	10:28	3	Double Read
					VISIT 6	17NOV2015	12:06	3	Double Read
					VISIT 7	23MAY2016	9:57	3	Double Read
					VISIT 8	24APR2017	9:04	3	Double Read
					VISIT 11	11MAY2020	8:33	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
					VISIT 7	23MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	06FEB2015	15:28	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
					VISIT 7	23MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
					VISIT 7	23MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	9:04	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 11	11MAY2020	8:33	N	Double Read
					Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
					VISIT 7	23MAY2016	9:57	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	N	Double Read
					Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	23MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	N	Double Read
					Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	23MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
					VISIT 7	23MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	N	Double Read
Fracture	4_5		General		Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
					VISIT 7	23MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	06FEB2015	15:28	12.82	Double Read
					VISIT 3A	20MAY2015	12:29	14.235	Double Read
					VISIT 4	08JUL2015	10:28	14.895	Double Read
					VISIT 6	17NOV2015	12:06	14.52	Double Read
					VISIT 7	23MAY2016	9:57	14.53	Double Read
					VISIT 8	24APR2017	9:04	15.59	Double Read
					VISIT 11	11MAY2020	8:33	14.55	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	06FEB2015	15:28	13.355	Double Read
					VISIT 3A	20MAY2015	12:29	13.835	Double Read
					VISIT 4	08JUL2015	10:28	13.81	Double Read
					VISIT 6	17NOV2015	12:06	15.3	Double Read
					VISIT 7	23MAY2016	9:57	14.31	Double Read
					VISIT 8	24APR2017	9:04	14.47	Double Read
					VISIT 11	11MAY2020	8:33	14.875	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	06FEB2015	15:28	14.725	Double Read
					VISIT 3A	20MAY2015	12:29	15.36	Double Read
					VISIT 4	08JUL2015	10:28	14.13	Double Read
					VISIT 6	17NOV2015	12:06	15.985	Double Read
					VISIT 7	23MAY2016	9:57	16.13	Double Read
					VISIT 8	24APR2017	9:04	15.82	Double Read
					VISIT 11	11MAY2020	8:33	14.04	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	06FEB2015	15:28	10.73785	Double Read
					VISIT 3A	20MAY2015	12:29	10.614	Double Read
					VISIT 4	08JUL2015	10:28	9.960995	Double Read
					VISIT 6	17NOV2015	12:06	10.76005	Double Read
					VISIT 7	23MAY2016	9:57	10.23423	Double Read
					VISIT 8	24APR2017	9:04	9.92794	Double Read
					VISIT 11	11MAY2020	8:33	11.58935	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	06FEB2015	15:28	10.6413	Double Read
					VISIT 3A	20MAY2015	12:29	9.83636	Double Read
					VISIT 4	08JUL2015	10:28	10.2019	Double Read
					VISIT 6	17NOV2015	12:06	10.42425	Double Read
					VISIT 7	23MAY2016	9:57	10.70285	Double Read
					VISIT 8	24APR2017	9:04	10.54945	Double Read
					VISIT 11	11MAY2020	8:33	10.366215	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	06FEB2015	15:28	11.5191	Double Read
					VISIT 3A	20MAY2015	12:29	10.82995	Double Read
					VISIT 4	08JUL2015	10:28	10.6537	Double Read
					VISIT 6	17NOV2015	12:06	10.4763	Double Read
					VISIT 7	23MAY2016	9:57	11.58185	Double Read
					VISIT 8	24APR2017	9:04	11.6039	Double Read
					VISIT 11	11MAY2020	8:33	10.06414	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
					VISIT 7	23MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
					VISIT 7	23MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
					VISIT 7	23MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
					VISIT 7	23MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
					VISIT 7	23MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
					VISIT 7	23MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	Y	Double Read
Normal lordotic LS	4_5		General		Baseline	06FEB2015	15:28	Y	Double Read
					VISIT 3A	20MAY2015	12:29	Y	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	Y	Double Read
					VISIT 7	23MAY2016	9:57	Y	Double Read
					VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	06FEB2015	15:28	0	Double Read
					VISIT 3A	20MAY2015	12:29	0	Double Read
					VISIT 4	08JUL2015	10:28	0	Double Read
					VISIT 6	17NOV2015	12:06	0	Double Read
					VISIT 7	23MAY2016	9:57	0	Double Read
					VISIT 8	24APR2017	9:04	0	Double Read
					VISIT 11	11MAY2020	8:33	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	06FEB2015	15:28	0	Double Read
					VISIT 3A	20MAY2015	12:29	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 4	08JUL2015	10:28	0	Double Read
					VISIT 6	17NOV2015	12:06	0	Double Read
					VISIT 7	23MAY2016	9:57	0	Double Read
					VISIT 8	24APR2017	9:04	0	Double Read
					VISIT 11	11MAY2020	8:33	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	06FEB2015	15:28	0	Double Read
					VISIT 3A	20MAY2015	12:29	0	Double Read
					VISIT 4	08JUL2015	10:28	0	Double Read
					VISIT 6	17NOV2015	12:06	0	Double Read
					VISIT 7	23MAY2016	9:57	0	Double Read
					VISIT 8	24APR2017	9:04	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 11	11MAY2020	8:33	0	Double Read
					Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
					VISIT 7	23MAY2016	9:57	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	N	Double Read
					Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	23MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	N	Double Read
					Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
					VISIT 7	23MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	9:04	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	N	Double Read
Relevant scoliosis	4_5		General		Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
					VISIT 7	23MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	9:04	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		VISIT 11	11MAY2020	8:33	N	Double Read
					Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
					VISIT 7	23MAY2016	9:57	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	N	Double Read
					Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read
					VISIT 6	17NOV2015	12:06	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	23MAY2016	9:57	N	Double Read
					VISIT 8	24APR2017	9:04	N	Double Read
					VISIT 11	11MAY2020	8:33	N	Double Read
					Baseline	06FEB2015	15:28	N	Double Read
					VISIT 3A	20MAY2015	12:29	N	Double Read
					VISIT 4	08JUL2015	10:28	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	06FEB2015	15:28	84.70416	Double Read
					VISIT 3A	20MAY2015	12:29	80.73472	Double Read
					VISIT 4	08JUL2015	10:28	79.21072	Double Read
					VISIT 6	17NOV2015	12:06	80.85696	Double Read
					VISIT 7	23MAY2016	9:57	82.74688	Double Read
					VISIT 8	24APR2017	9:04	81.81568	Double Read
					VISIT 11	11MAY2020	8:33	77.68544	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	06FEB2015	15:28	61.05376	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	20MAY2015	12:29	59.24832	Double Read
					VISIT 4	08JUL2015	10:28	61.33888	Double Read
					VISIT 6	17NOV2015	12:06	68.38064	Double Read
					VISIT 7	23MAY2016	9:57	67.36672	Double Read
					VISIT 8	24APR2017	9:04	63.22496	Double Read
					VISIT 11	11MAY2020	8:33	58.79248	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	VISIT 11	11MAY2020	8:33		Double Read
					Baseline	06FEB2015	15:28	71.21424	Double Read
					VISIT 3A	20MAY2015	12:29	68.47424	Double Read
					VISIT 4	08JUL2015	10:28	68.19504	Double Read
					VISIT 6	17NOV2015	12:06	73.63216	Double Read
					VISIT 7	23MAY2016	9:57	71.84032	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	24APR2017	9:04	74.09264	Double Read
					VISIT 11	11MAY2020	8:33	65.0384	Double Read
					Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	06FEB2015	15:28	lower	Double Read
					VISIT 3A	20MAY2015	12:29	lower	Double Read
					VISIT 4	08JUL2015	10:28	lower	Double Read
					VISIT 6	17NOV2015	12:06	lower	Double Read
					VISIT 7	23MAY2016	9:57	lower	Double Read
					VISIT 8	24APR2017	9:04	lower	Double Read
					VISIT 11	11MAY2020	8:33	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		VISIT 11	11MAY2020	8:33		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	06FEB2015	15:28	lower	Double Read
					VISIT 3A	20MAY2015	12:29	lower	Double Read
					VISIT 4	08JUL2015	10:28	lower	Double Read
					VISIT 6	17NOV2015	12:06	lower	Double Read
					VISIT 7	23MAY2016	9:57	lower	Double Read
					VISIT 8	24APR2017	9:04	lower	Double Read
					VISIT 11	11MAY2020	8:33	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	06FEB2015	15:28	4.2250246305	Double Read
					VISIT 3A	20MAY2015	12:29	5.1903448275	Double Read
					VISIT 4	08JUL2015	10:28	7.2529369797	Double Read
					VISIT 6	17NOV2015	12:06	3.8212536096	Double Read
					VISIT 7	23MAY2016	9:57	19.219092916	Double Read
					VISIT 8	24APR2017	9:04	8.1299609308	Double Read
					VISIT 11	11MAY2020	8:33	2.2996228979	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	06FEB2015	15:28	5.89346016647	Double Read
					VISIT 3A	20MAY2015	12:29	7.47246475285	Double Read
					VISIT 4	08JUL2015	10:28	7.7288941736	Double Read
					VISIT 6	17NOV2015	12:06	10.795916426	Double Read
					VISIT 7	23MAY2016	9:57	6.80029216919	Double Read
					VISIT 8	24APR2017	9:04	8.61540343128	Double Read
					VISIT 11	11MAY2020	8:33	7.7108748089	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	06FEB2015	15:28	17.895770341	Double Read
					VISIT 3A	20MAY2015	12:29	12.543414302	Double Read
					VISIT 4	08JUL2015	10:28	11.155549515	Double Read
					VISIT 6	17NOV2015	12:06	10.963084763	Double Read
					VISIT 7	23MAY2016	9:57	11.923655512	Double Read
					VISIT 8	24APR2017	9:04	7.4266417530	Double Read
					VISIT 11	11MAY2020	8:33	8.6518362493	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	06FEB2015	15:28	12922.5	Double Read
					VISIT 3A	20MAY2015	12:29	13596.0	Double Read
					VISIT 4	08JUL2015	10:28	13745.0	Double Read
					VISIT 6	17NOV2015	12:06	14034.5	Double Read
					VISIT 7	23MAY2016	9:57	15257.0	Double Read
					VISIT 8	24APR2017	9:04	15319.0	Double Read
					VISIT 11	11MAY2020	8:33	15485.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	06FEB2015	15:28	15740.5	Double Read
					VISIT 3A	20MAY2015	12:29	16237.0	Double Read
					VISIT 4	08JUL2015	10:28	16426.5	Double Read
					VISIT 6	17NOV2015	12:06	18460.5	Double Read
					VISIT 7	23MAY2016	9:57	18377.0	Double Read
					VISIT 8	24APR2017	9:04	17528.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0904 Age=58 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 11	11MAY2020	8:33	18052.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	06FEB2015	15:28	18860.0	Double Read
					VISIT 3A	20MAY2015	12:29	18744.5	Double Read
					VISIT 4	08JUL2015	10:28	18550.5	Double Read
					VISIT 6	17NOV2015	12:06	20328.0	Double Read
					VISIT 7	23MAY2016	9:57	22207.5	Double Read
					VISIT 8	24APR2017	9:04	21202.5	Double Read
					VISIT 11	11MAY2020	8:33	17500.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	06FEB2015	15:28		Double Read
					VISIT 3A	20MAY2015	12:29		Double Read
					VISIT 4	08JUL2015	10:28		Double Read
					VISIT 6	17NOV2015	12:06		Double Read
					VISIT 7	23MAY2016	9:57		Double Read
					VISIT 8	24APR2017	9:04		Double Read
					VISIT 11	11MAY2020	8:33		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	18MAR2015	15:33	3	Double Read
					VISIT 3A	24JUN2015	11:35	3	Double Read
					VISIT 4	10AUG2015	10:57	3	Double Read
					VISIT 6	21DEC2015	10:00	3	Double Read
					VISIT 7	20JUN2016	9:50	3	Double Read
					VISIT 8	19JUN2017	9:27	3	Double Read
					VISIT 11	25MAY2020	9:06	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	18MAR2015	15:33	2	Double Read
					VISIT 3A	24JUN2015	11:35	3	Double Read
					VISIT 4	10AUG2015	10:57	3	Double Read
					VISIT 6	21DEC2015	10:00	2	Double Read
					VISIT 7	20JUN2016	9:50	3	Double Read
					VISIT 8	19JUN2017	9:27	3	Double Read
					VISIT 11	25MAY2020	9:06	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	18MAR2015	15:33	3	Double Read
					VISIT 3A	24JUN2015	11:35	3	Double Read
					VISIT 4	10AUG2015	10:57	3	Double Read
					VISIT 6	21DEC2015	10:00	3	Double Read
					VISIT 7	20JUN2016	9:50	3	Double Read
					VISIT 8	19JUN2017	9:27	3	Double Read
					VISIT 11	25MAY2020	9:06	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	N	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	18MAR2015	15:33	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	N	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	N	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 11	25MAY2020	9:06	N	Double Read
					Baseline	18MAR2015	15:33	Y	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	N	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read
					Baseline	18MAR2015	15:33	Y	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	Y	Double Read
					VISIT 6	21DEC2015	10:00	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	20JUN2016	9:50	Y	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	Y	Double Read
					Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	N	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	N	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read
Fracture	4_5		General		Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	N	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	18MAR2015	15:33	13.37	Double Read
					VISIT 3A	24JUN2015	11:35	13.53	Double Read
					VISIT 4	10AUG2015	10:57	14.985	Double Read
					VISIT 6	21DEC2015	10:00	15.25	Double Read
					VISIT 7	20JUN2016	9:50	14.085	Double Read
					VISIT 8	19JUN2017	9:27	15.8	Double Read
					VISIT 11	25MAY2020	9:06	14.645	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	18MAR2015	15:33	13.15	Double Read
					VISIT 3A	24JUN2015	11:35	13.88	Double Read
					VISIT 4	10AUG2015	10:57	15.58	Double Read
					VISIT 6	21DEC2015	10:00	13.87	Double Read
					VISIT 7	20JUN2016	9:50	13.62	Double Read
					VISIT 8	19JUN2017	9:27	14.915	Double Read
					VISIT 11	25MAY2020	9:06	13.34	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	18MAR2015	15:33	12.27	Double Read
					VISIT 3A	24JUN2015	11:35	12.8	Double Read
					VISIT 4	10AUG2015	10:57	15.19	Double Read
					VISIT 6	21DEC2015	10:00	13.245	Double Read
					VISIT 7	20JUN2016	9:50	13.46	Double Read
					VISIT 8	19JUN2017	9:27	14.205	Double Read
					VISIT 11	25MAY2020	9:06	13.505	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	18MAR2015	15:33	7.545435	Double Read
					VISIT 3A	24JUN2015	11:35	9.060845	Double Read
					VISIT 4	10AUG2015	10:57	8.880165	Double Read
					VISIT 6	21DEC2015	10:00	8.51633	Double Read
					VISIT 7	20JUN2016	9:50	7.2193	Double Read
					VISIT 8	19JUN2017	9:27	7.83162	Double Read
					VISIT 11	25MAY2020	9:06	7.79429	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	18MAR2015	15:33	8.919925	Double Read
					VISIT 3A	24JUN2015	11:35	8.39421	Double Read
					VISIT 4	10AUG2015	10:57	9.07556	Double Read
					VISIT 6	21DEC2015	10:00	8.018805	Double Read
					VISIT 7	20JUN2016	9:50	8.79518	Double Read
					VISIT 8	19JUN2017	9:27	8.66431	Double Read
					VISIT 11	25MAY2020	9:06	7.0439	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	18MAR2015	15:33	11.11555	Double Read
					VISIT 3A	24JUN2015	11:35	9.867025	Double Read
					VISIT 4	10AUG2015	10:57	10.092585	Double Read
					VISIT 6	21DEC2015	10:00	9.827485	Double Read
					VISIT 7	20JUN2016	9:50	9.71175	Double Read
					VISIT 8	19JUN2017	9:27	9.05211	Double Read
					VISIT 11	25MAY2020	9:06	10.219605	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	N	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	N	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	N	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	N	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	N	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	N	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read
Normal lordotic LS	4_5		General		Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	N	Double Read
					VISIT 6	21DEC2015	10:00	Y	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	Y	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	18MAR2015	15:33	0	Double Read
					VISIT 3A	24JUN2015	11:35	0	Double Read
					VISIT 4	10AUG2015	10:57	0	Double Read
					VISIT 6	21DEC2015	10:00	0	Double Read
					VISIT 7	20JUN2016	9:50	0	Double Read
					VISIT 8	19JUN2017	9:27	0	Double Read
					VISIT 11	25MAY2020	9:06	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	18MAR2015	15:33	0	Double Read
					VISIT 3A	24JUN2015	11:35	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 4	10AUG2015	10:57	0	Double Read
					VISIT 6	21DEC2015	10:00	0	Double Read
					VISIT 7	20JUN2016	9:50	0	Double Read
					VISIT 8	19JUN2017	9:27	0	Double Read
					VISIT 11	25MAY2020	9:06	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	18MAR2015	15:33	0	Double Read
					VISIT 3A	24JUN2015	11:35	0	Double Read
					VISIT 4	10AUG2015	10:57	0	Double Read
					VISIT 6	21DEC2015	10:00	0	Double Read
					VISIT 7	20JUN2016	9:50	0	Double Read
					VISIT 8	19JUN2017	9:27	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 11	25MAY2020	9:06	0	Double Read
					Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	Y	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read
					Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	Y	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read
					Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	Y	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read
Relevant scoliosis	4_5		General		Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	N	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	N	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	N	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	18MAR2015	15:33	N	Double Read
					VISIT 3A	24JUN2015	11:35	N	Double Read
					VISIT 4	10AUG2015	10:57	N	Double Read
					VISIT 6	21DEC2015	10:00	N	Double Read
					VISIT 7	20JUN2016	9:50	N	Double Read
					VISIT 8	19JUN2017	9:27	N	Double Read
					VISIT 11	25MAY2020	9:06	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	18MAR2015	15:33	54.1	Double Read
					VISIT 3A	24JUN2015	11:35	61.26896	Double Read
					VISIT 4	10AUG2015	10:57	67.44256	Double Read
					VISIT 6	21DEC2015	10:00	57.47536	Double Read
					VISIT 7	20JUN2016	9:50	67.8248	Double Read
					VISIT 8	19JUN2017	9:27	59.27984	Double Read
					VISIT 11	25MAY2020	9:06	60.15856	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	18MAR2015	15:33	76.56	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	24JUN2015	11:35	84.43632	Double Read
					VISIT 4	10AUG2015	10:57	81.52416	Double Read
					VISIT 6	21DEC2015	10:00	79.33056	Double Read
					VISIT 7	20JUN2016	9:50	77.09504	Double Read
					VISIT 8	19JUN2017	9:27	73.97344	Double Read
					VISIT 11	25MAY2020	9:06	79.05504	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	VISIT 11	25MAY2020	9:06		Double Read
					Baseline	18MAR2015	15:33	74.41472	Double Read
					VISIT 3A	24JUN2015	11:35	68.8712	Double Read
					VISIT 4	10AUG2015	10:57	73.40592	Double Read
					VISIT 6	21DEC2015	10:00	72.432	Double Read
					VISIT 7	20JUN2016	9:50	69.82112	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	19JUN2017	9:27	68.46336	Double Read
					VISIT 11	25MAY2020	9:06	74.65024	Double Read
					Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	18MAR2015	15:33	higher	Double Read
					VISIT 3A	24JUN2015	11:35	higher	Double Read
					VISIT 4	10AUG2015	10:57	higher	Double Read
					VISIT 6	21DEC2015	10:00	higher	Double Read
					VISIT 7	20JUN2016	9:50	higher	Double Read
					VISIT 8	19JUN2017	9:27	higher	Double Read
					VISIT 11	25MAY2020	9:06	higher	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		VISIT 11	25MAY2020	9:06		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	18MAR2015	15:33	higher	Double Read
					VISIT 3A	24JUN2015	11:35	higher	Double Read
					VISIT 4	10AUG2015	10:57	higher	Double Read
					VISIT 6	21DEC2015	10:00	higher	Double Read
					VISIT 7	20JUN2016	9:50	higher	Double Read
					VISIT 8	19JUN2017	9:27	equal	Double Read
					VISIT 11	25MAY2020	9:06	higher	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	18MAR2015	15:33	7.5616239171	Double Read
					VISIT 3A	24JUN2015	11:35	12.586247664	Double Read
					VISIT 4	10AUG2015	10:57	8.9590827246	Double Read
					VISIT 6	21DEC2015	10:00	9.4983319177	Double Read
					VISIT 7	20JUN2016	9:50	9.4464209274	Double Read
					VISIT 8	19JUN2017	9:27	12.023305588	Double Read
					VISIT 11	25MAY2020	9:06	9.0906539833	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	18MAR2015	15:33	5.9000033973	Double Read
					VISIT 3A	24JUN2015	11:35	2	Double Read
					VISIT 4	10AUG2015	10:57	3.6783692882	Double Read
					VISIT 6	21DEC2015	10:00	6	Double Read
					VISIT 7	20JUN2016	9:50	9	Double Read
					VISIT 8	19JUN2017	9:27	4.1107525055	Double Read
					VISIT 11	25MAY2020	9:06	2	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	18MAR2015	15:33	10.184501443	Double Read
					VISIT 3A	24JUN2015	11:35	8.7764022422	Double Read
					VISIT 4	10AUG2015	10:57	9.2414744352	Double Read
					VISIT 6	21DEC2015	10:00	7.9070562255	Double Read
					VISIT 7	20JUN2016	9:50	8.1050314251	Double Read
					VISIT 8	19JUN2017	9:27	8.9587701715	Double Read
					VISIT 11	25MAY2020	9:06	5.6036419228	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	18MAR2015	15:33	11952.5	Double Read
					VISIT 3A	24JUN2015	11:35	11835.0	Double Read
					VISIT 4	10AUG2015	10:57	14114.0	Double Read
					VISIT 6	21DEC2015	10:00	13861.0	Double Read
					VISIT 7	20JUN2016	9:50	13172.5	Double Read
					VISIT 8	19JUN2017	9:27	13719.5	Double Read
					VISIT 11	25MAY2020	9:06	13439.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	18MAR2015	15:33	14294.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm ³) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	24JUN2015	11:35	14849.0	Double Read
					VISIT 4	10AUG2015	10:57	17526.5	Double Read
					VISIT 6	21DEC2015	10:00	15921.0	Double Read
					VISIT 7	20JUN2016	9:50	17231.0	Double Read
					VISIT 8	19JUN2017	9:27	16892.5	Double Read
					VISIT 11	25MAY2020	9:06	16926.0	Double Read
Volume (mm ³) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
Volume (mm ³) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	18MAR2015	15:33		Double Read
					VISIT 3A	24JUN2015	11:35		Double Read
					VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
Volume (mm ³) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	18MAR2015	15:33	14823.5	Double Read
					VISIT 3A	24JUN2015	11:35	16908.0	Double Read
					VISIT 4	10AUG2015	10:57	19886.0	Double Read
					VISIT 6	21DEC2015	10:00	18419.5	Double Read
					VISIT 7	20JUN2016	9:50	18659.5	Double Read
					VISIT 8	19JUN2017	9:27	18707.0	Double Read
Volume (mm ³) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	25MAY2020	9:06	16961.0	Double Read
					VISIT 3A	24JUN2015	11:35		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0905 Age=53 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	10AUG2015	10:57		Double Read
					VISIT 6	21DEC2015	10:00		Double Read
					VISIT 7	20JUN2016	9:50		Double Read
					VISIT 8	19JUN2017	9:27		Double Read
					VISIT 11	25MAY2020	9:06		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0906 Age=51 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	26MAR2015	17:05	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	26MAR2015	17:05	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	26MAR2015	17:05	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	26MAR2015	17:05	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	26MAR2015	17:05	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	26MAR2015	17:05	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	26MAR2015	17:05	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	26MAR2015	17:05	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	26MAR2015	17:05	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	26MAR2015	17:05	N	Double Read
Fracture	4_5		General		Baseline	26MAR2015	17:05	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	26MAR2015	17:05	11.465	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	26MAR2015	17:05	11.585	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	26MAR2015	17:05	12.44	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0906 Age=51 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	26MAR2015	17:05	7.233045	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	26MAR2015	17:05	8.52155	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	26MAR2015	17:05	11.2308	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	26MAR2015	17:05	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	26MAR2015	17:05	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	26MAR2015	17:05	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	26MAR2015	17:05	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	26MAR2015	17:05	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	26MAR2015	17:05	N	Double Read
Normal lordotic LS	4_5		General		Baseline	26MAR2015	17:05	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	26MAR2015	17:05	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	26MAR2015	17:05	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0906 Age=51 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	26MAR2015	17:05	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	26MAR2015	17:05	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	26MAR2015	17:05	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	26MAR2015	17:05	N	Double Read
Relevant scoliosis	4_5		General		Baseline	26MAR2015	17:05	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	26MAR2015	17:05	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	26MAR2015	17:05	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	26MAR2015	17:05	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	26MAR2015	17:05		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	26MAR2015	17:05	72.3656	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	26MAR2015	17:05		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	26MAR2015	17:05		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	26MAR2015	17:05	63.71504	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	26MAR2015	17:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0906 Age=51 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	26MAR2015	17:05		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	26MAR2015	17:05	81.83728	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	26MAR2015	17:05		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	26MAR2015	17:05		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	26MAR2015	17:05		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	26MAR2015	17:05		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	26MAR2015	17:05		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	26MAR2015	17:05	equal	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	26MAR2015	17:05		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	26MAR2015	17:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0906 Age=51 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	26MAR2015	17:05	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	26MAR2015	17:05		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	26MAR2015	17:05		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	26MAR2015	17:05		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	26MAR2015	17:05		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	26MAR2015	17:05		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	26MAR2015	17:05	7.8650586037	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	26MAR2015	17:05		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	26MAR2015	17:05		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	26MAR2015	17:05	6.02457618482	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	26MAR2015	17:05		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	26MAR2015	17:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0906 Age=51 Sex=Female Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	26MAR2015	17:05	13.8034992356	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	26MAR2015	17:05		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	26MAR2015	17:05		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	26MAR2015	17:05	7612.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	26MAR2015	17:05		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	26MAR2015	17:05		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	26MAR2015	17:05	10904.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	26MAR2015	17:05		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	26MAR2015	17:05		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	26MAR2015	17:05	13552.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	26MAR2015	17:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0907 Age=58 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	13APR2015	14:38	3	Double Read
					VISIT 4	26MAY2015	9:58	3	Double Read
					VISIT 6	09NOV2015	10:24	3	Double Read
					VISIT 7	04APR2016	10:43	3	Double Read
					VISIT 8	10APR2017	9:01	3	Double Read
					VISIT 11	12MAY2020	10:06	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	13APR2015	14:38	2	Double Read
					VISIT 4	26MAY2015	9:58	2	Double Read
					VISIT 6	09NOV2015	10:24	2	Double Read
					VISIT 7	04APR2016	10:43	3	Double Read
					VISIT 8	10APR2017	9:01	3	Double Read
					VISIT 11	12MAY2020	10:06	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	13APR2015	14:38	N	Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24	N	Double Read
					VISIT 7	04APR2016	10:43	N	Double Read
					VISIT 8	10APR2017	9:01	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0907 Age=58 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 11	12MAY2020	10:06	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	13APR2015	14:38	N	Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24	N	Double Read
					VISIT 7	04APR2016	10:43	N	Double Read
					VISIT 8	10APR2017	9:01	N	Double Read
					VISIT 11	12MAY2020	10:06	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	13APR2015	14:38	Y	Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24	N	Double Read
					VISIT 7	04APR2016	10:43	N	Double Read
					VISIT 8	10APR2017	9:01	N	Double Read
					VISIT 11	12MAY2020	10:06	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	13APR2015	14:38	N	Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24	N	Double Read
					VISIT 7	04APR2016	10:43	N	Double Read
					VISIT 8	10APR2017	9:01	N	Double Read
					VISIT 11	12MAY2020	10:06	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	13APR2015	14:38	N	Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24	N	Double Read
					VISIT 7	04APR2016	10:43	N	Double Read
					VISIT 8	10APR2017	9:01	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0907 Age=58 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 11	12MAY2020	10:06	N	Double Read
Fracture	5_S		General		Baseline	13APR2015	14:38	N	Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24	N	Double Read
					VISIT 7	04APR2016	10:43	N	Double Read
					VISIT 8	10APR2017	9:01	N	Double Read
					VISIT 11	12MAY2020	10:06	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	13APR2015	14:38	12.87	Double Read
					VISIT 4	26MAY2015	9:58	15.21	Double Read
					VISIT 6	09NOV2015	10:24	14.12	Double Read
					VISIT 7	04APR2016	10:43	14.025	Double Read
					VISIT 8	10APR2017	9:01	14.765	Double Read
					VISIT 11	12MAY2020	10:06	10.89	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	13APR2015	14:38	15.73	Double Read
					VISIT 4	26MAY2015	9:58	18.49	Double Read
					VISIT 6	09NOV2015	10:24	16.71	Double Read
					VISIT 7	04APR2016	10:43	16.215	Double Read
					VISIT 8	10APR2017	9:01	17.73	Double Read
					VISIT 11	12MAY2020	10:06	14.955	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0907 Age=58 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	13APR2015	14:38	10.363085	Double Read
					VISIT 4	26MAY2015	9:58	10.20675	Double Read
					VISIT 6	09NOV2015	10:24	10.331715	Double Read
					VISIT 7	04APR2016	10:43	10.29185	Double Read
					VISIT 8	10APR2017	9:01	11.26275	Double Read
					VISIT 11	12MAY2020	10:06	8.00243	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	13APR2015	14:38	12.1621	Double Read
					VISIT 4	26MAY2015	9:58	14.39485	Double Read
					VISIT 6	09NOV2015	10:24	13.4159	Double Read
					VISIT 7	04APR2016	10:43	13.23015	Double Read
					VISIT 8	10APR2017	9:01	13.14115	Double Read
					VISIT 11	12MAY2020	10:06	12.27895	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	13APR2015	14:38	N	Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24	N	Double Read
					VISIT 7	04APR2016	10:43	N	Double Read
					VISIT 8	10APR2017	9:01	N	Double Read
					VISIT 11	12MAY2020	10:06	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0907 Age=58 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	13APR2015	14:38	N	Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24	N	Double Read
					VISIT 7	04APR2016	10:43	N	Double Read
					VISIT 8	10APR2017	9:01	N	Double Read
					VISIT 11	12MAY2020	10:06	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	13APR2015	14:38	N	Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24	N	Double Read
					VISIT 7	04APR2016	10:43	N	Double Read
					VISIT 8	10APR2017	9:01	N	Double Read
					VISIT 11	12MAY2020	10:06	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	13APR2015	14:38	N	Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24	N	Double Read
					VISIT 7	04APR2016	10:43	N	Double Read
					VISIT 8	10APR2017	9:01	N	Double Read
					VISIT 11	12MAY2020	10:06	N	Double Read
Normal lordotic LS	5_S		General		Baseline	13APR2015	14:38	Y	Double Read
					VISIT 4	26MAY2015	9:58	Y	Double Read
					VISIT 6	09NOV2015	10:24	Y	Double Read
					VISIT 7	04APR2016	10:43	Y	Double Read
					VISIT 8	10APR2017	9:01	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0907 Age=58 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	5_S		General		VISIT 11	12MAY2020	10:06	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	13APR2015	14:38	0	Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24	0	Double Read
					VISIT 7	04APR2016	10:43	0	Double Read
					VISIT 8	10APR2017	9:01	0	Double Read
					VISIT 11	12MAY2020	10:06	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	13APR2015	14:38	0	Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24	0	Double Read
					VISIT 7	04APR2016	10:43	0	Double Read
					VISIT 8	10APR2017	9:01	0	Double Read
					VISIT 11	12MAY2020	10:06	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	13APR2015	14:38	N	Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24	N	Double Read
					VISIT 7	04APR2016	10:43	N	Double Read
					VISIT 8	10APR2017	9:01	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0907 Age=58 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 11	12MAY2020	10:06	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	13APR2015	14:38	N	Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24	N	Double Read
					VISIT 7	04APR2016	10:43	N	Double Read
					VISIT 8	10APR2017	9:01	N	Double Read
					VISIT 11	12MAY2020	10:06	N	Double Read
Relevant scoliosis	5_S		General		Baseline	13APR2015	14:38	N	Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24	N	Double Read
					VISIT 7	04APR2016	10:43	N	Double Read
					VISIT 8	10APR2017	9:01	N	Double Read
					VISIT 11	12MAY2020	10:06	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	13APR2015	14:38	N	Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24	N	Double Read
					VISIT 7	04APR2016	10:43	N	Double Read
					VISIT 8	10APR2017	9:01	N	Double Read
					VISIT 11	12MAY2020	10:06	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	13APR2015	14:38	N	Double Read
					VISIT 4	26MAY2015	9:58	N	Double Read
					VISIT 6	09NOV2015	10:24	N	Double Read
					VISIT 7	04APR2016	10:43	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0907 Age=58 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	10APR2017	9:01	N	Double Read
					VISIT 11	12MAY2020	10:06	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	13APR2015	14:38	58.94336	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0907 Age=58 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 4	26MAY2015	9:58	62.33488	Double Read
					VISIT 6	09NOV2015	10:24	65.39024	Double Read
					VISIT 7	04APR2016	10:43	67.14256	Double Read
					VISIT 8	10APR2017	9:01	70.51952	Double Read
					VISIT 11	12MAY2020	10:06	76.64992	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	13APR2015	14:38	75.59968	Double Read
					VISIT 4	26MAY2015	9:58	74.76784	Double Read
					VISIT 6	09NOV2015	10:24	74.59952	Double Read
					VISIT 7	04APR2016	10:43	75.80752	Double Read
					VISIT 8	10APR2017	9:01	75.04192	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	12MAY2020	10:06	64.73328	Double Read
					Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0907 Age=58 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0907 Age=58 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	13APR2015	14:38	lower	Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24	equal	Double Read
					VISIT 7	04APR2016	10:43	equal	Double Read
					VISIT 8	10APR2017	9:01	lower	Double Read
					VISIT 11	12MAY2020	10:06	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0907 Age=58 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0907 Age=58 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	13APR2015	14:38	8.1135926618	Double Read
					VISIT 4	26MAY2015	9:58	4.84926108375	Double Read
					VISIT 6	09NOV2015	10:24	11.2820112111	Double Read
					VISIT 7	04APR2016	10:43	14.9340580941	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0907 Age=58 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	10APR2017	9:01	12.4446679123	Double Read
					VISIT 11	12MAY2020	10:06	11.7717003567	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	13APR2015	14:38	13.9629692543	Double Read
					VISIT 4	26MAY2015	9:58	2.90470528283	Double Read
					VISIT 6	09NOV2015	10:24	6.02251741124	Double Read
					VISIT 7	04APR2016	10:43	14.8400883302	Double Read
					VISIT 8	10APR2017	9:01	8.99582809581	Double Read
					VISIT 11	12MAY2020	10:06	10.6681773399	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0907 Age=58 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0907 Age=58 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	13APR2015	14:38	14262.0	Double Read
					VISIT 4	26MAY2015	9:58	17044.0	Double Read
					VISIT 6	09NOV2015	10:24	15268.0	Double Read
					VISIT 7	04APR2016	10:43	15997.0	Double Read
					VISIT 8	10APR2017	9:01	15615.5	Double Read
					VISIT 11	12MAY2020	10:06	9814.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read
					VISIT 11	12MAY2020	10:06		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	13APR2015	14:38	20082.0	Double Read
					VISIT 4	26MAY2015	9:58	22250.5	Double Read
					VISIT 6	09NOV2015	10:24	20410.0	Double Read
					VISIT 7	04APR2016	10:43	21621.5	Double Read
					VISIT 8	10APR2017	9:01	22089.0	Double Read
					VISIT 11	12MAY2020	10:06	17030.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	13APR2015	14:38		Double Read
					VISIT 4	26MAY2015	9:58		Double Read
					VISIT 6	09NOV2015	10:24		Double Read
					VISIT 7	04APR2016	10:43		Double Read
					VISIT 8	10APR2017	9:01		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0907 Age=58 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	12MAY2020	10:06		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	05MAY2015	16:21	3	Double Read
					VISIT 3A	05AUG2015	10:55	3	Double Read
					VISIT 4	21SEP2015	9:46	3	Double Read
					VISIT 6	25JAN2016	9:57	3	Double Read
					VISIT 7	20JUL2016	9:12	3	Double Read
					VISIT 8	17JUL2017	9:31	3	Double Read
					VISIT 11	22JUN2020	8:05	3	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	05MAY2015	16:21	3	Double Read
					VISIT 3A	05AUG2015	10:55	3	Double Read
					VISIT 4	21SEP2015	9:46	3	Double Read
					VISIT 6	25JAN2016	9:57	3	Double Read
					VISIT 7	20JUL2016	9:12	3	Double Read
					VISIT 8	17JUL2017	9:31	3	Double Read
					VISIT 11	22JUN2020	8:05	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	05MAY2015	16:21	3	Double Read
					VISIT 3A	05AUG2015	10:55	3	Double Read
					VISIT 4	21SEP2015	9:46	3	Double Read
					VISIT 6	25JAN2016	9:57	3	Double Read
					VISIT 7	20JUL2016	9:12	3	Double Read
					VISIT 8	17JUL2017	9:31	3	Double Read
					VISIT 11	22JUN2020	8:05	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	05MAY2015	16:21	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
					VISIT 7	20JUL2016	9:12	N	Double Read
					VISIT 8	17JUL2017	9:31	N	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	05MAY2015	16:21	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
					VISIT 7	20JUL2016	9:12	N	Double Read
					VISIT 8	17JUL2017	9:31	N	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	05MAY2015	16:21	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
					VISIT 7	20JUL2016	9:12	N	Double Read
					VISIT 8	17JUL2017	9:31	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 11	22JUN2020	8:05	N	Double Read
					Baseline	05MAY2015	16:21	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
					VISIT 7	20JUL2016	9:12	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		VISIT 8	17JUL2017	9:31	Y	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read
					Baseline	05MAY2015	16:21	Y	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	20JUL2016	9:12	Y	Double Read
					VISIT 8	17JUL2017	9:31	Y	Double Read
					VISIT 11	22JUN2020	8:05	Y	Double Read
					Baseline	05MAY2015	16:21	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	20JUL2016	9:12	N	Double Read
					VISIT 8	17JUL2017	9:31	Y	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	05MAY2015	16:21	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
					VISIT 7	20JUL2016	9:12	N	Double Read
					VISIT 8	17JUL2017	9:31	N	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read
Fracture	4_5		General		Baseline	05MAY2015	16:21	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
					VISIT 7	20JUL2016	9:12	N	Double Read
					VISIT 8	17JUL2017	9:31	N	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	05MAY2015	16:21	11.925	Double Read
					VISIT 3A	05AUG2015	10:55	12.335	Double Read
					VISIT 4	21SEP2015	9:46	12.04	Double Read
					VISIT 6	25JAN2016	9:57	13.105	Double Read
					VISIT 7	20JUL2016	9:12	12.58	Double Read
					VISIT 8	17JUL2017	9:31	13.685	Double Read
					VISIT 11	22JUN2020	8:05	14.005	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	05MAY2015	16:21	12.82	Double Read
					VISIT 3A	05AUG2015	10:55	11.975	Double Read
					VISIT 4	21SEP2015	9:46	12.64	Double Read
					VISIT 6	25JAN2016	9:57	13.78	Double Read
					VISIT 7	20JUL2016	9:12	12.095	Double Read
					VISIT 8	17JUL2017	9:31	14.475	Double Read
					VISIT 11	22JUN2020	8:05	13.19	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	05MAY2015	16:21	12.67	Double Read
					VISIT 3A	05AUG2015	10:55	11.32	Double Read
					VISIT 4	21SEP2015	9:46	12.42	Double Read
					VISIT 6	25JAN2016	9:57	12.515	Double Read
					VISIT 7	20JUL2016	9:12	11.85	Double Read
					VISIT 8	17JUL2017	9:31	13.455	Double Read
					VISIT 11	22JUN2020	8:05	11.97	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	05MAY2015	16:21	9.101265	Double Read
					VISIT 3A	05AUG2015	10:55	9.21614	Double Read
					VISIT 4	21SEP2015	9:46	9.5845	Double Read
					VISIT 6	25JAN2016	9:57	9.74354	Double Read
					VISIT 7	20JUL2016	9:12	7.95224	Double Read
					VISIT 8	17JUL2017	9:31	9.58357	Double Read
					VISIT 11	22JUN2020	8:05	10.508	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	05MAY2015	16:21	10.2936	Double Read
					VISIT 3A	05AUG2015	10:55	9.903245	Double Read
					VISIT 4	21SEP2015	9:46	8.97187	Double Read
					VISIT 6	25JAN2016	9:57	10.36595	Double Read
					VISIT 7	20JUL2016	9:12	9.77064	Double Read
					VISIT 8	17JUL2017	9:31	10.094935	Double Read
					VISIT 11	22JUN2020	8:05	9.0007	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	05MAY2015	16:21	9.9562	Double Read
					VISIT 3A	05AUG2015	10:55	10.72225	Double Read
					VISIT 4	21SEP2015	9:46	10.485005	Double Read
					VISIT 6	25JAN2016	9:57	10.3056	Double Read
					VISIT 7	20JUL2016	9:12	10.55625	Double Read
					VISIT 8	17JUL2017	9:31	9.987	Double Read
					VISIT 11	22JUN2020	8:05	9.564265	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	05MAY2015	16:21	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
					VISIT 7	20JUL2016	9:12	N	Double Read
					VISIT 8	17JUL2017	9:31	N	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	05MAY2015	16:21	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
					VISIT 7	20JUL2016	9:12	N	Double Read
					VISIT 8	17JUL2017	9:31	N	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	05MAY2015	16:21	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
					VISIT 7	20JUL2016	9:12	N	Double Read
					VISIT 8	17JUL2017	9:31	N	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	05MAY2015	16:21	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
					VISIT 7	20JUL2016	9:12	N	Double Read
					VISIT 8	17JUL2017	9:31	N	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	05MAY2015	16:21	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
					VISIT 7	20JUL2016	9:12	N	Double Read
					VISIT 8	17JUL2017	9:31	N	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	05MAY2015	16:21	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
					VISIT 7	20JUL2016	9:12	N	Double Read
					VISIT 8	17JUL2017	9:31	N	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read
Normal lordotic LS	4_5		General		Baseline	05MAY2015	16:21	Y	Double Read
					VISIT 3A	05AUG2015	10:55	Y	Double Read
					VISIT 4	21SEP2015	9:46	Y	Double Read
					VISIT 6	25JAN2016	9:57	Y	Double Read
					VISIT 7	20JUL2016	9:12	Y	Double Read
					VISIT 8	17JUL2017	9:31	Y	Double Read
					VISIT 11	22JUN2020	8:05	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	05MAY2015	16:21	0	Double Read
					VISIT 3A	05AUG2015	10:55	0	Double Read
					VISIT 4	21SEP2015	9:46	0	Double Read
					VISIT 6	25JAN2016	9:57	0	Double Read
					VISIT 7	20JUL2016	9:12	0	Double Read
					VISIT 8	17JUL2017	9:31	0	Double Read
					VISIT 11	22JUN2020	8:05	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	05MAY2015	16:21	0	Double Read
					VISIT 3A	05AUG2015	10:55	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 4	21SEP2015	9:46	0	Double Read
					VISIT 6	25JAN2016	9:57	0	Double Read
					VISIT 7	20JUL2016	9:12	0	Double Read
					VISIT 8	17JUL2017	9:31	0	Double Read
					VISIT 11	22JUN2020	8:05	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	05MAY2015	16:21	0	Double Read
					VISIT 3A	05AUG2015	10:55	0	Double Read
					VISIT 4	21SEP2015	9:46	0	Double Read
					VISIT 6	25JAN2016	9:57	0	Double Read
					VISIT 7	20JUL2016	9:12	0	Double Read
					VISIT 8	17JUL2017	9:31	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 11	22JUN2020	8:05	0	Double Read
					Baseline	05MAY2015	16:21	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
					VISIT 7	20JUL2016	9:12	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	17JUL2017	9:31	N	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read
					Baseline	05MAY2015	16:21	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	20JUL2016	9:12	N	Double Read
					VISIT 8	17JUL2017	9:31	N	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
					VISIT 7	20JUL2016	9:12	N	Double Read
					VISIT 8	17JUL2017	9:31	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	17JUL2017	9:31	N	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read
Relevant scoliosis	4_5		General		Baseline	05MAY2015	16:21	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
					VISIT 7	20JUL2016	9:12	N	Double Read
					VISIT 8	17JUL2017	9:31	N	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	05MAY2015	16:21	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
					VISIT 7	20JUL2016	9:12	N	Double Read
					VISIT 8	17JUL2017	9:31	N	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	05MAY2015	16:21	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
					VISIT 7	20JUL2016	9:12	N	Double Read
					VISIT 8	17JUL2017	9:31	N	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	05MAY2015	16:21	N	Double Read
					VISIT 3A	05AUG2015	10:55	N	Double Read
					VISIT 4	21SEP2015	9:46	N	Double Read
					VISIT 6	25JAN2016	9:57	N	Double Read
					VISIT 7	20JUL2016	9:12	N	Double Read
					VISIT 8	17JUL2017	9:31	N	Double Read
					VISIT 11	22JUN2020	8:05	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 11	22JUN2020	8:05		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	05MAY2015	16:21	60.23808	Double Read
					VISIT 3A	05AUG2015	10:55	59.36944	Double Read
					VISIT 4	21SEP2015	9:46	62.39712	Double Read
					VISIT 6	25JAN2016	9:57	60.53232	Double Read
					VISIT 7	20JUL2016	9:12	58.86176	Double Read
					VISIT 8	17JUL2017	9:31	62.37184	Double Read
					VISIT 11	22JUN2020	8:05	60.4392	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 11	22JUN2020	8:05		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 11	22JUN2020	8:05		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	05MAY2015	16:21	61.34496	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	05AUG2015	10:55	58.61216	Double Read
					VISIT 4	21SEP2015	9:46	69.09552	Double Read
					VISIT 6	25JAN2016	9:57	74.36576	Double Read
					VISIT 7	20JUL2016	9:12	61.35104	Double Read
					VISIT 8	17JUL2017	9:31	67.208	Double Read
					VISIT 11	22JUN2020	8:05	61.4288	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	05MAY2015	16:21	64.39472	Double Read
					VISIT 3A	05AUG2015	10:55	65.17776	Double Read
					VISIT 4	21SEP2015	9:46	71.09104	Double Read
					VISIT 6	25JAN2016	9:57	74.68432	Double Read
					VISIT 7	20JUL2016	9:12	64.01232	Double Read
					VISIT 8	17JUL2017	9:31	68.1032	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	22JUN2020	8:05	62.55568	Double Read
					VISIT 3A	05AUG2015	10:55		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 11	22JUN2020	8:05		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 11	22JUN2020	8:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 11	22JUN2020	8:05		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	05MAY2015	16:21	equal	Double Read
					VISIT 3A	05AUG2015	10:55	equal	Double Read
					VISIT 4	21SEP2015	9:46	equal	Double Read
					VISIT 6	25JAN2016	9:57	equal	Double Read
					VISIT 7	20JUL2016	9:12	equal	Double Read
					VISIT 8	17JUL2017	9:31	equal	Double Read
					VISIT 11	22JUN2020	8:05	equal	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 11	22JUN2020	8:05		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 8	17JUL2017	9:31		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		VISIT 11	22JUN2020	8:05		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	05MAY2015	16:21	equal	Double Read
					VISIT 3A	05AUG2015	10:55	equal	Double Read
					VISIT 4	21SEP2015	9:46	lower	Double Read
					VISIT 6	25JAN2016	9:57	equal	Double Read
					VISIT 7	20JUL2016	9:12	equal	Double Read
					VISIT 8	17JUL2017	9:31	equal	Double Read
					VISIT 11	22JUN2020	8:05	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 11	22JUN2020	8:05		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 11	22JUN2020	8:05		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 11	22JUN2020	8:05		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 11	22JUN2020	8:05		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 11	22JUN2020	8:05		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	05MAY2015	16:21	7.1525462884	Double Read
					VISIT 3A	05AUG2015	10:55	6.8852318668	Double Read
					VISIT 4	21SEP2015	9:46	9.8373840665	Double Read
					VISIT 6	25JAN2016	9:57	9.9560183454	Double Read
					VISIT 7	20JUL2016	9:12	8.1025989468	Double Read
					VISIT 8	17JUL2017	9:31	3.9083675896	Double Read
					VISIT 11	22JUN2020	8:05	6.5907932733	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 11	22JUN2020	8:05		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 11	22JUN2020	8:05		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	05MAY2015	16:21	9.6907287242	Double Read
					VISIT 3A	05AUG2015	10:55	6.2537251571	Double Read
					VISIT 4	21SEP2015	9:46	9.5807168337	Double Read
					VISIT 6	25JAN2016	9:57	7.021117717	Double Read
					VISIT 7	20JUL2016	9:12	8.2573602853	Double Read
					VISIT 8	17JUL2017	9:31	4.8241888907	Double Read
					VISIT 11	22JUN2020	8:05	13.307769662	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 11	22JUN2020	8:05		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 11	22JUN2020	8:05		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	05MAY2015	16:21	10.373140818	Double Read
					VISIT 3A	05AUG2015	10:55	6.9041005605	Double Read
					VISIT 4	21SEP2015	9:46	7.1261287582	Double Read
					VISIT 6	25JAN2016	9:57	10.276881263	Double Read
					VISIT 7	20JUL2016	9:12	11.069583828	Double Read
					VISIT 8	17JUL2017	9:31	8.1486733480	Double Read
					VISIT 11	22JUN2020	8:05	10.250626804	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 11	22JUN2020	8:05		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	05MAY2015	16:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 11	22JUN2020	8:05		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	05MAY2015	16:21	9120.5	Double Read
					VISIT 3A	05AUG2015	10:55	9381.0	Double Read
					VISIT 4	21SEP2015	9:46	10879.5	Double Read
					VISIT 6	25JAN2016	9:57	10687.5	Double Read
					VISIT 7	20JUL2016	9:12	9887.5	Double Read
					VISIT 8	17JUL2017	9:31	11366.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	05MAY2015	16:21	13903.5	Double Read
					VISIT 3A	05AUG2015	10:55	11821.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 4	21SEP2015	9:46	13356.0	Double Read
					VISIT 6	25JAN2016	9:57	13720.0	Double Read
					VISIT 7	20JUL2016	9:12	12754.0	Double Read
					VISIT 8	17JUL2017	9:31	14487.0	Double Read
					VISIT 11	22JUN2020	8:05	13811.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read
					VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	05MAY2015	16:21	14280.5	Double Read
					VISIT 3A	05AUG2015	10:55	12392.5	Double Read
					VISIT 4	21SEP2015	9:46	14294.0	Double Read
					VISIT 6	25JAN2016	9:57	13746.0	Double Read
					VISIT 7	20JUL2016	9:12	13991.0	Double Read
					VISIT 8	17JUL2017	9:31	13634.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	22JUN2020	8:05	13044.5	Double Read
					Baseline	05MAY2015	16:21		Double Read
					VISIT 3A	05AUG2015	10:55		Double Read
					VISIT 4	21SEP2015	9:46		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0908 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 6	25JAN2016	9:57		Double Read
					VISIT 7	20JUL2016	9:12		Double Read
					VISIT 8	17JUL2017	9:31		Double Read
					VISIT 11	22JUN2020	8:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	11MAY2015	15:33	2	Double Read
					VISIT 3A	12AUG2015	11:14	3	Double Read
					VISIT 4	28SEP2015	9:28	3	Double Read
					VISIT 6	01FEB2016	9:35	3	Double Read
					VISIT 7	18JUL2016	9:53	3	Double Read
					VISIT 8	24JUL2017	9:29	3	Double Read
					VISIT 11	27JUL2020	9:05	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	15:33	3	Double Read
					VISIT 3A	12AUG2015	11:14	3	Double Read
					VISIT 4	28SEP2015	9:28	3	Double Read
					VISIT 6	01FEB2016	9:35	3	Double Read
					VISIT 7	18JUL2016	9:53	3	Double Read
					VISIT 8	24JUL2017	9:29	4	Double Read
					VISIT 11	27JUL2020	9:05	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	11MAY2015	15:33	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	12AUG2015	11:14	N	Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35	N	Double Read
					VISIT 7	18JUL2016	9:53	N	Double Read
					VISIT 8	24JUL2017	9:29	N	Double Read
					VISIT 11	27JUL2020	9:05	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	15:33	N	Double Read
					VISIT 3A	12AUG2015	11:14	N	Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35	N	Double Read
					VISIT 7	18JUL2016	9:53	N	Double Read
					VISIT 8	24JUL2017	9:29	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	27JUL2020	9:05	N	Double Read
					Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
					Baseline	11MAY2015	15:33	Y	Double Read
					VISIT 3A	12AUG2015	11:14	N	Double Read
					VISIT 4	28SEP2015	9:28	Y	Double Read
					VISIT 6	01FEB2016	9:35	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	18JUL2016	9:53	N	Double Read
					VISIT 8	24JUL2017	9:29	Y	Double Read
					VISIT 11	27JUL2020	9:05	Y	Double Read
					Baseline	11MAY2015	15:33	N	Double Read
					VISIT 3A	12AUG2015	11:14	N	Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	18JUL2016	9:53	N	Double Read
					VISIT 8	24JUL2017	9:29	N	Double Read
					VISIT 11	27JUL2020	9:05	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	11MAY2015	15:33	N	Double Read
					VISIT 3A	12AUG2015	11:14	N	Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35	N	Double Read
					VISIT 7	18JUL2016	9:53	N	Double Read
					VISIT 8	24JUL2017	9:29	N	Double Read
					VISIT 11	27JUL2020	9:05	N	Double Read
Fracture	5_S		General		Baseline	11MAY2015	15:33	N	Double Read
					VISIT 3A	12AUG2015	11:14	N	Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35	N	Double Read
					VISIT 7	18JUL2016	9:53	N	Double Read
					VISIT 8	24JUL2017	9:29	N	Double Read
					VISIT 11	27JUL2020	9:05	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11MAY2015	15:33	10.89	Double Read
					VISIT 3A	12AUG2015	11:14	10.885	Double Read
					VISIT 4	28SEP2015	9:28	12.905	Double Read
					VISIT 6	01FEB2016	9:35	11.545	Double Read
					VISIT 7	18JUL2016	9:53	12.09	Double Read
					VISIT 8	24JUL2017	9:29	13.165	Double Read
					VISIT 11	27JUL2020	9:05	11.785	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11MAY2015	15:33	11.665	Double Read
					VISIT 3A	12AUG2015	11:14	12.27	Double Read
					VISIT 4	28SEP2015	9:28	13.185	Double Read
					VISIT 6	01FEB2016	9:35	12.3	Double Read
					VISIT 7	18JUL2016	9:53	12.79	Double Read
					VISIT 8	24JUL2017	9:29	13.435	Double Read
					VISIT 11	27JUL2020	9:05	11.825	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11MAY2015	15:33	7.70889	Double Read
					VISIT 3A	12AUG2015	11:14	7.259485	Double Read
					VISIT 4	28SEP2015	9:28	6.772165	Double Read
					VISIT 6	01FEB2016	9:35	7.642145	Double Read
					VISIT 7	18JUL2016	9:53	7.66934	Double Read
					VISIT 8	24JUL2017	9:29	7.04527	Double Read
					VISIT 11	27JUL2020	9:05	7.82027	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11MAY2015	15:33	10.01186	Double Read
					VISIT 3A	12AUG2015	11:14	9.74218	Double Read
					VISIT 4	28SEP2015	9:28	10.17375	Double Read
					VISIT 6	01FEB2016	9:35	9.46884	Double Read
					VISIT 7	18JUL2016	9:53	10.0518	Double Read
					VISIT 8	24JUL2017	9:29	10.14732	Double Read
					VISIT 11	27JUL2020	9:05	9.875115	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	11MAY2015	15:33	N	Double Read
					VISIT 3A	12AUG2015	11:14	N	Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35	N	Double Read
					VISIT 7	18JUL2016	9:53	N	Double Read
					VISIT 8	24JUL2017	9:29	N	Double Read
					VISIT 11	27JUL2020	9:05	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	15:33	N	Double Read
					VISIT 3A	12AUG2015	11:14	N	Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35	N	Double Read
					VISIT 7	18JUL2016	9:53	N	Double Read
					VISIT 8	24JUL2017	9:29	N	Double Read
					VISIT 11	27JUL2020	9:05	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	11MAY2015	15:33	N	Double Read
					VISIT 3A	12AUG2015	11:14	N	Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35	N	Double Read
					VISIT 7	18JUL2016	9:53	N	Double Read
					VISIT 8	24JUL2017	9:29	N	Double Read
					VISIT 11	27JUL2020	9:05	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	15:33	N	Double Read
					VISIT 3A	12AUG2015	11:14	N	Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35	N	Double Read
					VISIT 7	18JUL2016	9:53	N	Double Read
					VISIT 8	24JUL2017	9:29	N	Double Read
					VISIT 11	27JUL2020	9:05	N	Double Read
Normal lordotic LS	5_S		General		Baseline	11MAY2015	15:33	Y	Double Read
					VISIT 3A	12AUG2015	11:14	Y	Double Read
					VISIT 4	28SEP2015	9:28	Y	Double Read
					VISIT 6	01FEB2016	9:35	Y	Double Read
					VISIT 7	18JUL2016	9:53	Y	Double Read
					VISIT 8	24JUL2017	9:29	Y	Double Read
					VISIT 11	27JUL2020	9:05	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	11MAY2015	15:33	0	Double Read
					VISIT 3A	12AUG2015	11:14	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	28SEP2015	9:28	2	Double Read
					VISIT 6	01FEB2016	9:35	0	Double Read
					VISIT 7	18JUL2016	9:53	0	Double Read
					VISIT 8	24JUL2017	9:29	0	Double Read
					VISIT 11	27JUL2020	9:05	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	15:33	0	Double Read
					VISIT 3A	12AUG2015	11:14	0	Double Read
					VISIT 4	28SEP2015	9:28	0	Double Read
					VISIT 6	01FEB2016	9:35	0	Double Read
					VISIT 7	18JUL2016	9:53	0	Double Read
					VISIT 8	24JUL2017	9:29	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 11	27JUL2020	9:05	0	Double Read
					Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
					Baseline	11MAY2015	15:33	N	Double Read
					VISIT 3A	12AUG2015	11:14	N	Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	18JUL2016	9:53	N	Double Read
					VISIT 8	24JUL2017	9:29	N	Double Read
					VISIT 11	27JUL2020	9:05	N	Double Read
					VISIT 3A	12AUG2015	11:14	N	Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35	N	Double Read
					VISIT 7	18JUL2016	9:53	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	24JUL2017	9:29	N	Double Read
					VISIT 11	27JUL2020	9:05	N	Double Read
Relevant scoliosis	5_S		General		Baseline	11MAY2015	15:33	N	Double Read
					VISIT 3A	12AUG2015	11:14	N	Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35	N	Double Read
					VISIT 7	18JUL2016	9:53	N	Double Read
					VISIT 8	24JUL2017	9:29	N	Double Read
					VISIT 11	27JUL2020	9:05	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	11MAY2015	15:33	N	Double Read
					VISIT 3A	12AUG2015	11:14	N	Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35	N	Double Read
					VISIT 7	18JUL2016	9:53	N	Double Read
					VISIT 8	24JUL2017	9:29	N	Double Read
					VISIT 11	27JUL2020	9:05	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	15:33	N	Double Read
					VISIT 3A	12AUG2015	11:14	N	Double Read
					VISIT 4	28SEP2015	9:28	N	Double Read
					VISIT 6	01FEB2016	9:35	N	Double Read
					VISIT 7	18JUL2016	9:53	N	Double Read
					VISIT 8	24JUL2017	9:29	N	Double Read
					VISIT 11	27JUL2020	9:05	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11MAY2015	15:33	60.4032	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	12AUG2015	11:14	58.47728	Double Read
					VISIT 4	28SEP2015	9:28	63.09056	Double Read
					VISIT 6	01FEB2016	9:35	61.24656	Double Read
					VISIT 7	18JUL2016	9:53	57.08	Double Read
					VISIT 8	24JUL2017	9:29	59.92528	Double Read
					VISIT 11	27JUL2020	9:05	56.55904	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11MAY2015	15:33	61.07792	Double Read
					VISIT 3A	12AUG2015	11:14	60.06368	Double Read
					VISIT 4	28SEP2015	9:28	60.38912	Double Read
					VISIT 6	01FEB2016	9:35	58.48768	Double Read
					VISIT 7	18JUL2016	9:53	58.80592	Double Read
					VISIT 8	24JUL2017	9:29	62.90608	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	27JUL2020	9:05	53.65328	Double Read
					VISIT 3A	12AUG2015	11:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	27JUL2020	9:05		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	11MAY2015	15:33	higher	Double Read
					VISIT 3A	12AUG2015	11:14	equal	Double Read
					VISIT 4	28SEP2015	9:28	equal	Double Read
					VISIT 6	01FEB2016	9:35	higher	Double Read
					VISIT 7	18JUL2016	9:53	higher	Double Read
					VISIT 8	24JUL2017	9:29	higher	Double Read
					VISIT 11	27JUL2020	9:05	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11MAY2015	15:33	10.1360421267	Double Read
					VISIT 3A	12AUG2015	11:14	7.12487854595	Double Read
					VISIT 4	28SEP2015	9:28	3.69960251401	Double Read
					VISIT 6	01FEB2016	9:35	10.4184338373	Double Read
					VISIT 7	18JUL2016	9:53	4.60779344318	Double Read
					VISIT 8	24JUL2017	9:29	8.14936640055	Double Read
					VISIT 11	27JUL2020	9:05	10.4500900289	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11MAY2015	15:33	7.9974520129	Double Read
					VISIT 3A	12AUG2015	11:14	6.5743230847	Double Read
					VISIT 4	28SEP2015	9:28	6.6247664345	Double Read
					VISIT 6	01FEB2016	9:35	8.1329301851	Double Read
					VISIT 7	18JUL2016	9:53	5.9817020553	Double Read
					VISIT 8	24JUL2017	9:29	8.3103516222	Double Read
					VISIT 11	27JUL2020	9:05	5.3058875488	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	11MAY2015	15:33	9333.0	Double Read
					VISIT 3A	12AUG2015	11:14	8600.5	Double Read
					VISIT 4	28SEP2015	9:28	9454.5	Double Read
					VISIT 6	01FEB2016	9:35	9256.5	Double Read
					VISIT 7	18JUL2016	9:53	9541.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	24JUL2017	9:29	9574.0	Double Read
					VISIT 11	27JUL2020	9:05	9488.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read
					VISIT 11	27JUL2020	9:05		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	11MAY2015	15:33	13649.5	Double Read
					VISIT 3A	12AUG2015	11:14	12718.5	Double Read
					VISIT 4	28SEP2015	9:28	13413.0	Double Read
					VISIT 6	01FEB2016	9:35	13305.0	Double Read
					VISIT 7	18JUL2016	9:53	14068.0	Double Read
					VISIT 8	24JUL2017	9:29	14217.5	Double Read
					VISIT 11	27JUL2020	9:05	14258.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	11MAY2015	15:33		Double Read
					VISIT 3A	12AUG2015	11:14		Double Read
					VISIT 4	28SEP2015	9:28		Double Read
					VISIT 6	01FEB2016	9:35		Double Read
					VISIT 7	18JUL2016	9:53		Double Read
					VISIT 8	24JUL2017	9:29		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0909 Age=53 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	27JUL2020	9:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0910 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	31AUG2015	16:15		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	31AUG2015	16:15	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	31AUG2015	16:15	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	31AUG2015	16:15		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	31AUG2015	16:15	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	31AUG2015	16:15	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	31AUG2015	16:15		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	31AUG2015	16:15	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	31AUG2015	16:15	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	31AUG2015	16:15	N	Double Read
Fracture	5_S		General		Baseline	31AUG2015	16:15	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	31AUG2015	16:15		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	31AUG2015	16:15	16.065	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	31AUG2015	16:15	20.65	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0910 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	31AUG2015	16:15		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	31AUG2015	16:15	9.034575	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	31AUG2015	16:15	15.14155	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	31AUG2015	16:15		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	31AUG2015	16:15	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	31AUG2015	16:15	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	31AUG2015	16:15		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	31AUG2015	16:15	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	31AUG2015	16:15	N	Double Read
Normal lordotic LS	5_S		General		Baseline	31AUG2015	16:15	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	31AUG2015	16:15		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	31AUG2015	16:15	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0910 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	31AUG2015	16:15	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	31AUG2015	16:15		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	31AUG2015	16:15	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	31AUG2015	16:15	N	Double Read
Relevant scoliosis	5_S		General		Baseline	31AUG2015	16:15	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	31AUG2015	16:15		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	31AUG2015	16:15	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	31AUG2015	16:15	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	31AUG2015	16:15		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	31AUG2015	16:15		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	31AUG2015	16:15		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	31AUG2015	16:15		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	31AUG2015	16:15	63.10368	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	31AUG2015	16:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0910 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	31AUG2015	16:15		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	31AUG2015	16:15	79.4064	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	31AUG2015	16:15		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	31AUG2015	16:15		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	31AUG2015	16:15		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	31AUG2015	16:15		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	31AUG2015	16:15		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	31AUG2015	16:15		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	31AUG2015	16:15		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	31AUG2015	16:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0910 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	31AUG2015	16:15	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	31AUG2015	16:15		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	31AUG2015	16:15		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	31AUG2015	16:15		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	31AUG2015	16:15		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	31AUG2015	16:15		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	31AUG2015	16:15		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	31AUG2015	16:15		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	31AUG2015	16:15		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	31AUG2015	16:15	13.3961882113	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	31AUG2015	16:15		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	31AUG2015	16:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0910 Age=54 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	31AUG2015	16:15	16.0986580602	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	31AUG2015	16:15		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	31AUG2015	16:15		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	31AUG2015	16:15		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	31AUG2015	16:15		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	31AUG2015	16:15		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	31AUG2015	16:15	16909.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	31AUG2015	16:15		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	31AUG2015	16:15		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	31AUG2015	16:15	27991.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	31AUG2015	16:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	15OCT2015	11:27	3	Double Read
					VISIT 3A	13JAN2016	10:36	3	Double Read
					VISIT 4	22FEB2016	10:19	3	Double Read
					VISIT 6	04JUL2016	13:26	4	Double Read
					VISIT 7	16JAN2017	9:29	3	Double Read
					VISIT 8	29JAN2018	9:21	3	Double Read
					VISIT 11	18JAN2021	8:58	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15OCT2015	11:27	3	Double Read
					VISIT 3A	13JAN2016	10:36	3	Double Read
					VISIT 4	22FEB2016	10:19	3	Double Read
					VISIT 6	04JUL2016	13:26	3	Double Read
					VISIT 7	16JAN2017	9:29	3	Double Read
					VISIT 8	29JAN2018	9:21	3	Double Read
					VISIT 11	18JAN2021	8:58	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	15OCT2015	11:27	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	13JAN2016	10:36	N	Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26	N	Double Read
					VISIT 7	16JAN2017	9:29	N	Double Read
					VISIT 8	29JAN2018	9:21	N	Double Read
					VISIT 11	18JAN2021	8:58	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15OCT2015	11:27	N	Double Read
					VISIT 3A	13JAN2016	10:36	N	Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26	N	Double Read
					VISIT 7	16JAN2017	9:29	N	Double Read
					VISIT 8	29JAN2018	9:21	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	18JAN2021	8:58	N	Double Read
					Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
					Baseline	15OCT2015	11:27	Y	Double Read
					VISIT 3A	13JAN2016	10:36	N	Double Read
					VISIT 4	22FEB2016	10:19	Y	Double Read
					VISIT 6	04JUL2016	13:26	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	16JAN2017	9:29	N	Double Read
					VISIT 8	29JAN2018	9:21	N	Double Read
					VISIT 11	18JAN2021	8:58	N	Double Read
					Baseline	15OCT2015	11:27	N	Double Read
					VISIT 3A	13JAN2016	10:36	N	Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	16JAN2017	9:29	N	Double Read
					VISIT 8	29JAN2018	9:21	N	Double Read
					VISIT 11	18JAN2021	8:58	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	15OCT2015	11:27	N	Double Read
					VISIT 3A	13JAN2016	10:36	N	Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26	N	Double Read
					VISIT 7	16JAN2017	9:29	N	Double Read
					VISIT 8	29JAN2018	9:21	N	Double Read
					VISIT 11	18JAN2021	8:58	N	Double Read
Fracture	5_S		General		Baseline	15OCT2015	11:27	N	Double Read
					VISIT 3A	13JAN2016	10:36	N	Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26	N	Double Read
					VISIT 7	16JAN2017	9:29	N	Double Read
					VISIT 8	29JAN2018	9:21	N	Double Read
					VISIT 11	18JAN2021	8:58	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15OCT2015	11:27	12.935	Double Read
					VISIT 3A	13JAN2016	10:36	13.09	Double Read
					VISIT 4	22FEB2016	10:19	13.815	Double Read
					VISIT 6	04JUL2016	13:26	13.28	Double Read
					VISIT 7	16JAN2017	9:29	13.22	Double Read
					VISIT 8	29JAN2018	9:21	12.215	Double Read
					VISIT 11	18JAN2021	8:58	13.08	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15OCT2015	11:27	13.77	Double Read
					VISIT 3A	13JAN2016	10:36	12.685	Double Read
					VISIT 4	22FEB2016	10:19	14.85	Double Read
					VISIT 6	04JUL2016	13:26	13.815	Double Read
					VISIT 7	16JAN2017	9:29	13.86	Double Read
					VISIT 8	29JAN2018	9:21	13.055	Double Read
					VISIT 11	18JAN2021	8:58	14.6	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15OCT2015	11:27	8.70007	Double Read
					VISIT 3A	13JAN2016	10:36	9.594305	Double Read
					VISIT 4	22FEB2016	10:19	9.547795	Double Read
					VISIT 6	04JUL2016	13:26	8.470445	Double Read
					VISIT 7	16JAN2017	9:29	8.899315	Double Read
					VISIT 8	29JAN2018	9:21	9.48159	Double Read
					VISIT 11	18JAN2021	8:58	9.78673	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15OCT2015	11:27	10.34095	Double Read
					VISIT 3A	13JAN2016	10:36	10.53155	Double Read
					VISIT 4	22FEB2016	10:19	10.5391	Double Read
					VISIT 6	04JUL2016	13:26	10.72455	Double Read
					VISIT 7	16JAN2017	9:29	10.97195	Double Read
					VISIT 8	29JAN2018	9:21	11.19065	Double Read
					VISIT 11	18JAN2021	8:58	11.23245	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	15OCT2015	11:27	N	Double Read
					VISIT 3A	13JAN2016	10:36	N	Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26	N	Double Read
					VISIT 7	16JAN2017	9:29	N	Double Read
					VISIT 8	29JAN2018	9:21	N	Double Read
					VISIT 11	18JAN2021	8:58	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15OCT2015	11:27	N	Double Read
					VISIT 3A	13JAN2016	10:36	N	Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26	N	Double Read
					VISIT 7	16JAN2017	9:29	N	Double Read
					VISIT 8	29JAN2018	9:21	N	Double Read
					VISIT 11	18JAN2021	8:58	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	15OCT2015	11:27	N	Double Read
					VISIT 3A	13JAN2016	10:36	N	Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26	N	Double Read
					VISIT 7	16JAN2017	9:29	N	Double Read
					VISIT 8	29JAN2018	9:21	N	Double Read
					VISIT 11	18JAN2021	8:58	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15OCT2015	11:27	N	Double Read
					VISIT 3A	13JAN2016	10:36	N	Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26	N	Double Read
					VISIT 7	16JAN2017	9:29	N	Double Read
					VISIT 8	29JAN2018	9:21	N	Double Read
					VISIT 11	18JAN2021	8:58	N	Double Read
Normal lordotic LS	5_S		General		Baseline	15OCT2015	11:27	Y	Double Read
					VISIT 3A	13JAN2016	10:36	Y	Double Read
					VISIT 4	22FEB2016	10:19	Y	Double Read
					VISIT 6	04JUL2016	13:26	Y	Double Read
					VISIT 7	16JAN2017	9:29	Y	Double Read
					VISIT 8	29JAN2018	9:21	Y	Double Read
					VISIT 11	18JAN2021	8:58	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	15OCT2015	11:27	0	Double Read
					VISIT 3A	13JAN2016	10:36	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	22FEB2016	10:19	0	Double Read
					VISIT 6	04JUL2016	13:26	0	Double Read
					VISIT 7	16JAN2017	9:29	0	Double Read
					VISIT 8	29JAN2018	9:21	0	Double Read
					VISIT 11	18JAN2021	8:58	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15OCT2015	11:27	0	Double Read
					VISIT 3A	13JAN2016	10:36	0	Double Read
					VISIT 4	22FEB2016	10:19	0	Double Read
					VISIT 6	04JUL2016	13:26	0	Double Read
					VISIT 7	16JAN2017	9:29	0	Double Read
					VISIT 8	29JAN2018	9:21	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 11	18JAN2021	8:58	0	Double Read
					Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
					Baseline	15OCT2015	11:27	N	Double Read
					VISIT 3A	13JAN2016	10:36	N	Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	16JAN2017	9:29	N	Double Read
					VISIT 8	29JAN2018	9:21	N	Double Read
					VISIT 11	18JAN2021	8:58	N	Double Read
					VISIT 3A	13JAN2016	10:36	N	Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26	N	Double Read
					VISIT 7	16JAN2017	9:29	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	29JAN2018	9:21	N	Double Read
					VISIT 11	18JAN2021	8:58	N	Double Read
Relevant scoliosis	5_S		General		Baseline	15OCT2015	11:27	N	Double Read
					VISIT 3A	13JAN2016	10:36	N	Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26	N	Double Read
					VISIT 7	16JAN2017	9:29	N	Double Read
					VISIT 8	29JAN2018	9:21	N	Double Read
					VISIT 11	18JAN2021	8:58	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	15OCT2015	11:27	N	Double Read
					VISIT 3A	13JAN2016	10:36	N	Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26	N	Double Read
					VISIT 7	16JAN2017	9:29	N	Double Read
					VISIT 8	29JAN2018	9:21	N	Double Read
					VISIT 11	18JAN2021	8:58	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	15OCT2015	11:27	N	Double Read
					VISIT 3A	13JAN2016	10:36	N	Double Read
					VISIT 4	22FEB2016	10:19	N	Double Read
					VISIT 6	04JUL2016	13:26	N	Double Read
					VISIT 7	16JAN2017	9:29	N	Double Read
					VISIT 8	29JAN2018	9:21	N	Double Read
					VISIT 11	18JAN2021	8:58	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15OCT2015	11:27	60.51248	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	13JAN2016	10:36	61.10768	Double Read
					VISIT 4	22FEB2016	10:19	69.7848	Double Read
					VISIT 6	04JUL2016	13:26	63.21664	Double Read
					VISIT 7	16JAN2017	9:29	63.2712	Double Read
					VISIT 8	29JAN2018	9:21	60.91888	Double Read
					VISIT 11	18JAN2021	8:58	63.27488	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15OCT2015	11:27	70.5576	Double Read
					VISIT 3A	13JAN2016	10:36	65.62336	Double Read
					VISIT 4	22FEB2016	10:19	70.56768	Double Read
					VISIT 6	04JUL2016	13:26	68.61344	Double Read
					VISIT 7	16JAN2017	9:29	66.8704	Double Read
					VISIT 8	29JAN2018	9:21	69.10528	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	18JAN2021	8:58	61.97696	Double Read
					VISIT 3A	13JAN2016	10:36		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	18JAN2021	8:58		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	15OCT2015	11:27	lower	Double Read
					VISIT 3A	13JAN2016	10:36	equal	Double Read
					VISIT 4	22FEB2016	10:19	equal	Double Read
					VISIT 6	04JUL2016	13:26	lower	Double Read
					VISIT 7	16JAN2017	9:29	lower	Double Read
					VISIT 8	29JAN2018	9:21	lower	Double Read
					VISIT 11	18JAN2021	8:58	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15OCT2015	11:27	11.076120265	Double Read
					VISIT 3A	13JAN2016	10:36	15.5446916935	Double Read
					VISIT 4	22FEB2016	10:19	10.9808799049	Double Read
					VISIT 6	04JUL2016	13:26	7.67393918804	Double Read
					VISIT 7	16JAN2017	9:29	4.73548496688	Double Read
					VISIT 8	29JAN2018	9:21	7.51782571768	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	VISIT 11	18JAN2021	8:58	9.08782062171	Double Read
					Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15OCT2015	11:27	13.825853575	Double Read
					VISIT 3A	13JAN2016	10:36	3.9484355359	Double Read
					VISIT 4	22FEB2016	10:19	6.7575743162	Double Read
					VISIT 6	04JUL2016	13:26	8.5716935620	Double Read
					VISIT 7	16JAN2017	9:29	10.758165449	Double Read
					VISIT 8	29JAN2018	9:21	10.871411584	Double Read
					VISIT 11	18JAN2021	8:58	5.5536674027	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	15OCT2015	11:27	10799.5	Double Read
					VISIT 3A	13JAN2016	10:36	11134.5	Double Read
					VISIT 4	22FEB2016	10:19	11099.0	Double Read
					VISIT 6	04JUL2016	13:26	11125.5	Double Read
					VISIT 7	16JAN2017	9:29	11378.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	29JAN2018	9:21	10425.5	Double Read
					VISIT 11	18JAN2021	8:58	10551.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read
					VISIT 11	18JAN2021	8:58		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	15OCT2015	11:27	14632.5	Double Read
					VISIT 3A	13JAN2016	10:36	13793.0	Double Read
					VISIT 4	22FEB2016	10:19	15223.0	Double Read
					VISIT 6	04JUL2016	13:26	15123.5	Double Read
					VISIT 7	16JAN2017	9:29	15381.5	Double Read
					VISIT 8	29JAN2018	9:21	14023.0	Double Read
					VISIT 11	18JAN2021	8:58	15372.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	15OCT2015	11:27		Double Read
					VISIT 3A	13JAN2016	10:36		Double Read
					VISIT 4	22FEB2016	10:19		Double Read
					VISIT 6	04JUL2016	13:26		Double Read
					VISIT 7	16JAN2017	9:29		Double Read
					VISIT 8	29JAN2018	9:21		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0911 Age=26 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	18JAN2021	8:58		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	19OCT2015	15:04	3	Double Read
					VISIT 3A	20JAN2016	10:19	3	Double Read
					VISIT 4	29FEB2016	10:34	3	Double Read
					VISIT 6	25JUL2016	9:13	3	Double Read
					VISIT 7	23JAN2017	9:22	4	Double Read
					VISIT 8	15JAN2018	8:46	4	Double Read
					VISIT 11	25JAN2021	8:52	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	19OCT2015	15:04	2	Double Read
					VISIT 3A	20JAN2016	10:19	2	Double Read
					VISIT 4	29FEB2016	10:34	2	Double Read
					VISIT 6	25JUL2016	9:13	2	Double Read
					VISIT 7	23JAN2017	9:22	3	Double Read
					VISIT 8	15JAN2018	8:46	2	Double Read
					VISIT 11	25JAN2021	8:52	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	19OCT2015	15:04	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	20JAN2016	10:19	N	Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13	N	Double Read
					VISIT 7	23JAN2017	9:22	N	Double Read
					VISIT 8	15JAN2018	8:46	N	Double Read
					VISIT 11	25JAN2021	8:52	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	19OCT2015	15:04	N	Double Read
					VISIT 3A	20JAN2016	10:19	N	Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13	N	Double Read
					VISIT 7	23JAN2017	9:22	N	Double Read
					VISIT 8	15JAN2018	8:46	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	25JAN2021	8:52	N	Double Read
					Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
					Baseline	19OCT2015	15:04	Y	Double Read
					VISIT 3A	20JAN2016	10:19	N	Double Read
					VISIT 4	29FEB2016	10:34	Y	Double Read
					VISIT 6	25JUL2016	9:13	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	23JAN2017	9:22	Y	Double Read
					VISIT 8	15JAN2018	8:46	Y	Double Read
					VISIT 11	25JAN2021	8:52	Y	Double Read
					Baseline	19OCT2015	15:04	N	Double Read
					VISIT 3A	20JAN2016	10:19	N	Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	23JAN2017	9:22	N	Double Read
					VISIT 8	15JAN2018	8:46	N	Double Read
					VISIT 11	25JAN2021	8:52	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	19OCT2015	15:04	N	Double Read
					VISIT 3A	20JAN2016	10:19	N	Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13	N	Double Read
					VISIT 7	23JAN2017	9:22	N	Double Read
					VISIT 8	15JAN2018	8:46	N	Double Read
					VISIT 11	25JAN2021	8:52	N	Double Read
Fracture	5_S		General		Baseline	19OCT2015	15:04	N	Double Read
					VISIT 3A	20JAN2016	10:19	N	Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13	N	Double Read
					VISIT 7	23JAN2017	9:22	N	Double Read
					VISIT 8	15JAN2018	8:46	N	Double Read
					VISIT 11	25JAN2021	8:52	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	19OCT2015	15:04	10.235	Double Read
					VISIT 3A	20JAN2016	10:19	11.505	Double Read
					VISIT 4	29FEB2016	10:34	13.09	Double Read
					VISIT 6	25JUL2016	9:13	12.845	Double Read
					VISIT 7	23JAN2017	9:22	13.555	Double Read
					VISIT 8	15JAN2018	8:46	12.27	Double Read
					VISIT 11	25JAN2021	8:52	12.445	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	19OCT2015	15:04	14.96	Double Read
					VISIT 3A	20JAN2016	10:19	15.235	Double Read
					VISIT 4	29FEB2016	10:34	16.63	Double Read
					VISIT 6	25JUL2016	9:13	17.08	Double Read
					VISIT 7	23JAN2017	9:22	16.385	Double Read
					VISIT 8	15JAN2018	8:46	16.03	Double Read
					VISIT 11	25JAN2021	8:52	16.535	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	19OCT2015	15:04	9.177445	Double Read
					VISIT 3A	20JAN2016	10:19	8.303605	Double Read
					VISIT 4	29FEB2016	10:34	9.350905	Double Read
					VISIT 6	25JUL2016	9:13	8.47905	Double Read
					VISIT 7	23JAN2017	9:22	9.084225	Double Read
					VISIT 8	15JAN2018	8:46	9.69168	Double Read
					VISIT 11	25JAN2021	8:52	9.291315	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	19OCT2015	15:04	13.11915	Double Read
					VISIT 3A	20JAN2016	10:19	13.5008	Double Read
					VISIT 4	29FEB2016	10:34	13.7952	Double Read
					VISIT 6	25JUL2016	9:13	13.2051	Double Read
					VISIT 7	23JAN2017	9:22	13.3961	Double Read
					VISIT 8	15JAN2018	8:46	13.2701	Double Read
					VISIT 11	25JAN2021	8:52	13.9385	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	19OCT2015	15:04	N	Double Read
					VISIT 3A	20JAN2016	10:19	N	Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13	N	Double Read
					VISIT 7	23JAN2017	9:22	N	Double Read
					VISIT 8	15JAN2018	8:46	N	Double Read
					VISIT 11	25JAN2021	8:52	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	19OCT2015	15:04	N	Double Read
					VISIT 3A	20JAN2016	10:19	N	Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13	N	Double Read
					VISIT 7	23JAN2017	9:22	N	Double Read
					VISIT 8	15JAN2018	8:46	N	Double Read
					VISIT 11	25JAN2021	8:52	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	19OCT2015	15:04	N	Double Read
					VISIT 3A	20JAN2016	10:19	N	Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13	N	Double Read
					VISIT 7	23JAN2017	9:22	N	Double Read
					VISIT 8	15JAN2018	8:46	N	Double Read
					VISIT 11	25JAN2021	8:52	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	19OCT2015	15:04	N	Double Read
					VISIT 3A	20JAN2016	10:19	N	Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13	N	Double Read
					VISIT 7	23JAN2017	9:22	N	Double Read
					VISIT 8	15JAN2018	8:46	N	Double Read
					VISIT 11	25JAN2021	8:52	N	Double Read
Normal lordotic LS	5_S		General		Baseline	19OCT2015	15:04	Y	Double Read
					VISIT 3A	20JAN2016	10:19	Y	Double Read
					VISIT 4	29FEB2016	10:34	Y	Double Read
					VISIT 6	25JUL2016	9:13	Y	Double Read
					VISIT 7	23JAN2017	9:22	Y	Double Read
					VISIT 8	15JAN2018	8:46	Y	Double Read
					VISIT 11	25JAN2021	8:52	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	19OCT2015	15:04	0	Double Read
					VISIT 3A	20JAN2016	10:19	3	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	29FEB2016	10:34	0	Double Read
					VISIT 6	25JUL2016	9:13	1	Double Read
					VISIT 7	23JAN2017	9:22	2	Double Read
					VISIT 8	15JAN2018	8:46	1	Double Read
					VISIT 11	25JAN2021	8:52	1	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	19OCT2015	15:04	0	Double Read
					VISIT 3A	20JAN2016	10:19	0	Double Read
					VISIT 4	29FEB2016	10:34	0	Double Read
					VISIT 6	25JUL2016	9:13	0	Double Read
					VISIT 7	23JAN2017	9:22	0	Double Read
					VISIT 8	15JAN2018	8:46	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 11	25JAN2021	8:52	0	Double Read
					Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
					Baseline	19OCT2015	15:04	N	Double Read
					VISIT 3A	20JAN2016	10:19	N	Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	23JAN2017	9:22	N	Double Read
					VISIT 8	15JAN2018	8:46	N	Double Read
					VISIT 11	25JAN2021	8:52	N	Double Read
					Baseline	19OCT2015	15:04	N	Double Read
					VISIT 3A	20JAN2016	10:19	N	Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13	N	Double Read
					VISIT 7	23JAN2017	9:22	N	Double Read
					VISIT 8	15JAN2018	8:46	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	15JAN2018	8:46	N	Double Read
					VISIT 11	25JAN2021	8:52	N	Double Read
Relevant scoliosis	5_S		General		Baseline	19OCT2015	15:04	N	Double Read
					VISIT 3A	20JAN2016	10:19	N	Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13	N	Double Read
					VISIT 7	23JAN2017	9:22	N	Double Read
					VISIT 8	15JAN2018	8:46	N	Double Read
					VISIT 11	25JAN2021	8:52	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	19OCT2015	15:04	N	Double Read
					VISIT 3A	20JAN2016	10:19	N	Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13	N	Double Read
					VISIT 7	23JAN2017	9:22	N	Double Read
					VISIT 8	15JAN2018	8:46	N	Double Read
					VISIT 11	25JAN2021	8:52	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	19OCT2015	15:04	N	Double Read
					VISIT 3A	20JAN2016	10:19	N	Double Read
					VISIT 4	29FEB2016	10:34	N	Double Read
					VISIT 6	25JUL2016	9:13	N	Double Read
					VISIT 7	23JAN2017	9:22	N	Double Read
					VISIT 8	15JAN2018	8:46	N	Double Read
					VISIT 11	25JAN2021	8:52	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	19OCT2015	15:04	70.66432	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	20JAN2016	10:19	73.03856	Double Read
					VISIT 4	29FEB2016	10:34	84.32896	Double Read
					VISIT 6	25JUL2016	9:13	75.5408	Double Read
					VISIT 7	23JAN2017	9:22	70.75856	Double Read
					VISIT 8	15JAN2018	8:46	68.04544	Double Read
					VISIT 11	25JAN2021	8:52	73.14976	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	19OCT2015	15:04	94.7216	Double Read
					VISIT 3A	20JAN2016	10:19	94.99056	Double Read
					VISIT 4	29FEB2016	10:34	99.26	Double Read
					VISIT 6	25JUL2016	9:13	94.06112	Double Read
					VISIT 7	23JAN2017	9:22	93.2408	Double Read
					VISIT 8	15JAN2018	8:46	93.068	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	25JAN2021	8:52	87.62784	Double Read
					VISIT 3A	20JAN2016	10:19		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 8	15JAN2018	8:46		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	25JAN2021	8:52		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	19OCT2015	15:04	lower	Double Read
					VISIT 3A	20JAN2016	10:19	lower	Double Read
					VISIT 4	29FEB2016	10:34	lower	Double Read
					VISIT 6	25JUL2016	9:13	lower	Double Read
					VISIT 7	23JAN2017	9:22	lower	Double Read
					VISIT 8	15JAN2018	8:46	lower	Double Read
					VISIT 11	25JAN2021	8:52	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	19OCT2015	15:04	8.5121589943	Double Read
					VISIT 3A	20JAN2016	10:19	5.2193307287	Double Read
					VISIT 4	29FEB2016	10:34	8.6254051299	Double Read
					VISIT 6	25JUL2016	9:13	7.3985935111	Double Read
					VISIT 7	23JAN2017	9:22	2.1764701885	Double Read
					VISIT 8	15JAN2018	8:46	8.1223101749	Double Read
					VISIT 11	25JAN2021	8:52	8.5701036181	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	19OCT2015	15:04	9.7389774078	Double Read
					VISIT 3A	20JAN2016	10:19	6.7622829964	Double Read
					VISIT 4	29FEB2016	10:34	16.848241888	Double Read
					VISIT 6	25JUL2016	9:13	14.472566672	Double Read
					VISIT 7	23JAN2017	9:22	5.8790963139	Double Read
					VISIT 8	15JAN2018	8:46	8.5043179887	Double Read
					VISIT 11	25JAN2021	8:52	16.046679123	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	19OCT2015	15:04	10458.0	Double Read
					VISIT 3A	20JAN2016	10:19	10778.0	Double Read
					VISIT 4	29FEB2016	10:34	12466.0	Double Read
					VISIT 6	25JUL2016	9:13	12114.5	Double Read
					VISIT 7	23JAN2017	9:22	13755.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	15JAN2018	8:46	12114.5	Double Read
					VISIT 11	25JAN2021	8:52	12298.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read
					VISIT 11	25JAN2021	8:52		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	19OCT2015	15:04	17482.5	Double Read
					VISIT 3A	20JAN2016	10:19	18363.5	Double Read
					VISIT 4	29FEB2016	10:34	19805.5	Double Read
					VISIT 6	25JUL2016	9:13	20673.5	Double Read
					VISIT 7	23JAN2017	9:22	20039.5	Double Read
					VISIT 8	15JAN2018	8:46	19223.0	Double Read
					VISIT 11	25JAN2021	8:52	21005.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	19OCT2015	15:04		Double Read
					VISIT 3A	20JAN2016	10:19		Double Read
					VISIT 4	29FEB2016	10:34		Double Read
					VISIT 6	25JUL2016	9:13		Double Read
					VISIT 7	23JAN2017	9:22		Double Read
					VISIT 8	15JAN2018	8:46		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0912 Age=40 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	25JAN2021	8:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	26NOV2015	13:47	2	Double Read
					VISIT 3A	17FEB2016	10:24	2	Double Read
					VISIT 4	04APR2016	15:14	2	Double Read
					VISIT 6	01AUG2016	10:56	2	Double Read
					VISIT 7	30JAN2017	13:26	2	Double Read
					VISIT 8	05FEB2018	12:47	2	Double Read
					VISIT 11	08MAR2021	9:04	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	26NOV2015	13:47	3	Double Read
					VISIT 3A	17FEB2016	10:24	3	Double Read
					VISIT 4	04APR2016	15:14	3	Double Read
					VISIT 6	01AUG2016	10:56	3	Double Read
					VISIT 7	30JAN2017	13:26	3	Double Read
					VISIT 8	05FEB2018	12:47	3	Double Read
					VISIT 11	08MAR2021	9:04	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	26NOV2015	13:47	2	Double Read
					VISIT 3A	17FEB2016	10:24	1	Double Read
					VISIT 4	04APR2016	15:14	2	Double Read
					VISIT 6	01AUG2016	10:56	1	Double Read
					VISIT 7	30JAN2017	13:26	2	Double Read
					VISIT 8	05FEB2018	12:47	1	Double Read
					VISIT 11	08MAR2021	9:04	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	26NOV2015	13:47	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
					VISIT 7	30JAN2017	13:26	N	Double Read
					VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	26NOV2015	13:47	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
					VISIT 7	30JAN2017	13:26	N	Double Read
					VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	26NOV2015	13:47	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
					VISIT 7	30JAN2017	13:26	N	Double Read
					VISIT 8	05FEB2018	12:47	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 11	08MAR2021	9:04	N	Double Read
					Baseline	26NOV2015	13:47	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
					VISIT 7	30JAN2017	13:26	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read
					Baseline	26NOV2015	13:47	Y	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	Y	Double Read
					VISIT 6	01AUG2016	10:56	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	30JAN2017	13:26	Y	Double Read
					VISIT 8	05FEB2018	12:47	Y	Double Read
					VISIT 11	08MAR2021	9:04	Y	Double Read
					Baseline	26NOV2015	13:47	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	30JAN2017	13:26	N	Double Read
					VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	26NOV2015	13:47	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
					VISIT 7	30JAN2017	13:26	N	Double Read
					VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read
Fracture	4_5		General		Baseline	26NOV2015	13:47	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
					VISIT 7	30JAN2017	13:26	N	Double Read
					VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	26NOV2015	13:47	13.955	Double Read
					VISIT 3A	17FEB2016	10:24	14.905	Double Read
					VISIT 4	04APR2016	15:14	16.275	Double Read
					VISIT 6	01AUG2016	10:56	14.52	Double Read
					VISIT 7	30JAN2017	13:26	15.195	Double Read
					VISIT 8	05FEB2018	12:47	14.82	Double Read
					VISIT 11	08MAR2021	9:04	36.635	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	26NOV2015	13:47	12.075	Double Read
					VISIT 3A	17FEB2016	10:24	10.63	Double Read
					VISIT 4	04APR2016	15:14	12.765	Double Read
					VISIT 6	01AUG2016	10:56	11.685	Double Read
					VISIT 7	30JAN2017	13:26	11.12	Double Read
					VISIT 8	05FEB2018	12:47	10.685	Double Read
					VISIT 11	08MAR2021	9:04	12.3	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	26NOV2015	13:47	12.64	Double Read
					VISIT 3A	17FEB2016	10:24	12.98	Double Read
					VISIT 4	04APR2016	15:14	13.165	Double Read
					VISIT 6	01AUG2016	10:56	14.32	Double Read
					VISIT 7	30JAN2017	13:26	12.57	Double Read
					VISIT 8	05FEB2018	12:47	13.465	Double Read
					VISIT 11	08MAR2021	9:04	14.15	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	26NOV2015	13:47	9.58148	Double Read
					VISIT 3A	17FEB2016	10:24	10.4372	Double Read
					VISIT 4	04APR2016	15:14	9.08623	Double Read
					VISIT 6	01AUG2016	10:56	10.25295	Double Read
					VISIT 7	30JAN2017	13:26	9.56814	Double Read
					VISIT 8	05FEB2018	12:47	9.86406	Double Read
					VISIT 11	08MAR2021	9:04	11.48975	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	26NOV2015	13:47	9.15237	Double Read
					VISIT 3A	17FEB2016	10:24	9.164275	Double Read
					VISIT 4	04APR2016	15:14	8.444135	Double Read
					VISIT 6	01AUG2016	10:56	9.02088	Double Read
					VISIT 7	30JAN2017	13:26	8.560805	Double Read
					VISIT 8	05FEB2018	12:47	8.499705	Double Read
					VISIT 11	08MAR2021	9:04	9.112575	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	26NOV2015	13:47	10.4076	Double Read
					VISIT 3A	17FEB2016	10:24	11.25315	Double Read
					VISIT 4	04APR2016	15:14	10.6411	Double Read
					VISIT 6	01AUG2016	10:56	10.55785	Double Read
					VISIT 7	30JAN2017	13:26	9.938875	Double Read
					VISIT 8	05FEB2018	12:47	10.7364	Double Read
					VISIT 11	08MAR2021	9:04	11.20095	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	26NOV2015	13:47	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
					VISIT 7	30JAN2017	13:26	N	Double Read
					VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	26NOV2015	13:47	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
					VISIT 7	30JAN2017	13:26	N	Double Read
					VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	26NOV2015	13:47	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
					VISIT 7	30JAN2017	13:26	N	Double Read
					VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	26NOV2015	13:47	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
					VISIT 7	30JAN2017	13:26	N	Double Read
					VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	26NOV2015	13:47	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
					VISIT 7	30JAN2017	13:26	N	Double Read
					VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	26NOV2015	13:47	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
					VISIT 7	30JAN2017	13:26	N	Double Read
					VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read
Normal lordotic LS	4_5		General		Baseline	26NOV2015	13:47	Y	Double Read
					VISIT 3A	17FEB2016	10:24	Y	Double Read
					VISIT 4	04APR2016	15:14	Y	Double Read
					VISIT 6	01AUG2016	10:56	Y	Double Read
					VISIT 7	30JAN2017	13:26	Y	Double Read
					VISIT 8	05FEB2018	12:47	Y	Double Read
					VISIT 11	08MAR2021	9:04	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	26NOV2015	13:47	0	Double Read
					VISIT 3A	17FEB2016	10:24	0	Double Read
					VISIT 4	04APR2016	15:14	0	Double Read
					VISIT 6	01AUG2016	10:56	0	Double Read
					VISIT 7	30JAN2017	13:26	0	Double Read
					VISIT 8	05FEB2018	12:47	0	Double Read
					VISIT 11	08MAR2021	9:04	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	26NOV2015	13:47	0	Double Read
					VISIT 3A	17FEB2016	10:24	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 4	04APR2016	15:14	0	Double Read
					VISIT 6	01AUG2016	10:56	0	Double Read
					VISIT 7	30JAN2017	13:26	0	Double Read
					VISIT 8	05FEB2018	12:47	0	Double Read
					VISIT 11	08MAR2021	9:04	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	26NOV2015	13:47	0	Double Read
					VISIT 3A	17FEB2016	10:24	0	Double Read
					VISIT 4	04APR2016	15:14	0	Double Read
					VISIT 6	01AUG2016	10:56	0	Double Read
					VISIT 7	30JAN2017	13:26	0	Double Read
					VISIT 8	05FEB2018	12:47	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 11	08MAR2021	9:04	0	Double Read
					Baseline	26NOV2015	13:47	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
					VISIT 7	30JAN2017	13:26	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read
					Baseline	26NOV2015	13:47	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	30JAN2017	13:26	N	Double Read
					VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
					VISIT 7	30JAN2017	13:26	N	Double Read
					VISIT 8	05FEB2018	12:47	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read
Relevant scoliosis	4_5		General		Baseline	26NOV2015	13:47	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
					VISIT 7	30JAN2017	13:26	N	Double Read
					VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	26NOV2015	13:47	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
					VISIT 7	30JAN2017	13:26	N	Double Read
					VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	26NOV2015	13:47	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
					VISIT 7	30JAN2017	13:26	N	Double Read
					VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	26NOV2015	13:47	N	Double Read
					VISIT 3A	17FEB2016	10:24	N	Double Read
					VISIT 4	04APR2016	15:14	N	Double Read
					VISIT 6	01AUG2016	10:56	N	Double Read
					VISIT 7	30JAN2017	13:26	N	Double Read
					VISIT 8	05FEB2018	12:47	N	Double Read
					VISIT 11	08MAR2021	9:04	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	26NOV2015	13:47	109.5568	Double Read
					VISIT 3A	17FEB2016	10:24	110.8912	Double Read
					VISIT 4	04APR2016	15:14	110.25696	Double Read
					VISIT 6	01AUG2016	10:56	108.13504	Double Read
					VISIT 7	30JAN2017	13:26	111.20576	Double Read
					VISIT 8	05FEB2018	12:47	101.73488	Double Read
					VISIT 11	08MAR2021	9:04	103.52512	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	26NOV2015	13:47	69.92512	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	17FEB2016	10:24	69.86864	Double Read
					VISIT 4	04APR2016	15:14	66.8136	Double Read
					VISIT 6	01AUG2016	10:56	69.84912	Double Read
					VISIT 7	30JAN2017	13:26	71.11584	Double Read
					VISIT 8	05FEB2018	12:47	68.50688	Double Read
					VISIT 11	08MAR2021	9:04	77.61152	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	26NOV2015	13:47	118.39744	Double Read
					VISIT 3A	17FEB2016	10:24	117.47856	Double Read
					VISIT 4	04APR2016	15:14	116.01344	Double Read
					VISIT 6	01AUG2016	10:56	112.3488	Double Read
					VISIT 7	30JAN2017	13:26	116.9472	Double Read
					VISIT 8	05FEB2018	12:47	106.68976	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	08MAR2021	9:04	108.47376	Double Read
					VISIT 3A	17FEB2016	10:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	26NOV2015	13:47	lower	Double Read
					VISIT 3A	17FEB2016	10:24	lower	Double Read
					VISIT 4	04APR2016	15:14	lower	Double Read
					VISIT 6	01AUG2016	10:56	lower	Double Read
					VISIT 7	30JAN2017	13:26	lower	Double Read
					VISIT 8	05FEB2018	12:47	lower	Double Read
					VISIT 11	08MAR2021	9:04	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 8	05FEB2018	12:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		VISIT 11	08MAR2021	9:04		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	26NOV2015	13:47	lower	Double Read
					VISIT 3A	17FEB2016	10:24	lower	Double Read
					VISIT 4	04APR2016	15:14	lower	Double Read
					VISIT 6	01AUG2016	10:56	lower	Double Read
					VISIT 7	30JAN2017	13:26	lower	Double Read
					VISIT 8	05FEB2018	12:47	lower	Double Read
					VISIT 11	08MAR2021	9:04	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	26NOV2015	13:47	2.7744725666	Double Read
					VISIT 3A	17FEB2016	10:24	4.5621063359	Double Read
					VISIT 4	04APR2016	15:14	4.4542619330	Double Read
					VISIT 6	01AUG2016	10:56	2.2468625785	Double Read
					VISIT 7	30JAN2017	13:26	1.9121046373	Double Read
					VISIT 8	05FEB2018	12:47	4.9261083743	Double Read
					VISIT 11	08MAR2021	9:04	4.7111397995	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	26NOV2015	13:47	9.8587599796	Double Read
					VISIT 3A	17FEB2016	10:24	11.045218277	Double Read
					VISIT 4	04APR2016	15:14	12.037825717	Double Read
					VISIT 6	01AUG2016	10:56	11.134703584	Double Read
					VISIT 7	30JAN2017	13:26	8.6888941735	Double Read
					VISIT 8	05FEB2018	12:47	15.205435705	Double Read
					VISIT 11	08MAR2021	9:04	4.7601290980	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	26NOV2015	13:47	5.2415695600	Double Read
					VISIT 3A	17FEB2016	10:24	4.5014438593	Double Read
					VISIT 4	04APR2016	15:14	5.7026397146	Double Read
					VISIT 6	01AUG2016	10:56	10.135321895	Double Read
					VISIT 7	30JAN2017	13:26	3.9878036351	Double Read
					VISIT 8	05FEB2018	12:47	11.012970952	Double Read
					VISIT 11	08MAR2021	9:04	6.0358960421	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	26NOV2015	13:47	10682.5	Double Read
					VISIT 3A	17FEB2016	10:24	12286.0	Double Read
					VISIT 4	04APR2016	15:14	11488.5	Double Read
					VISIT 6	01AUG2016	10:56	12393.0	Double Read
					VISIT 7	30JAN2017	13:26	12248.5	Double Read
					VISIT 8	05FEB2018	12:47	11451.5	Double Read
					VISIT 11	08MAR2021	9:04	13468.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	26NOV2015	13:47	12879.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	17FEB2016	10:24	12578.0	Double Read
					VISIT 4	04APR2016	15:14	14099.0	Double Read
					VISIT 6	01AUG2016	10:56	14068.5	Double Read
					VISIT 7	30JAN2017	13:26	12302.0	Double Read
					VISIT 8	05FEB2018	12:47	11878.5	Double Read
					VISIT 11	08MAR2021	9:04	13720.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read
					VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	26NOV2015	13:47	15569.0	Double Read
					VISIT 3A	17FEB2016	10:24	15802.5	Double Read
					VISIT 4	04APR2016	15:14	17395.5	Double Read
					VISIT 6	01AUG2016	10:56	18227.5	Double Read
					VISIT 7	30JAN2017	13:26	15928.5	Double Read
					VISIT 8	05FEB2018	12:47	15957.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	26NOV2015	13:47		Double Read
					VISIT 3A	17FEB2016	10:24		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0913 Age=28 Sex=Female Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	04APR2016	15:14		Double Read
					VISIT 6	01AUG2016	10:56		Double Read
					VISIT 7	30JAN2017	13:26		Double Read
					VISIT 8	05FEB2018	12:47		Double Read
					VISIT 11	08MAR2021	9:04		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0914 Age=35 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	04JAN2016	13:46	3	Double Read
					VISIT 4	15FEB2016	9:24	3	Double Read
					VISIT 6	27JUN2016	9:01	3	Double Read
					VISIT 7	09JAN2017	9:05	4	Double Read
					VISIT 8	08JAN2018	9:27	3	Double Read
					VISIT 11	11JAN2021	9:15	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04JAN2016	13:46	2	Double Read
					VISIT 4	15FEB2016	9:24	2	Double Read
					VISIT 6	27JUN2016	9:01	3	Double Read
					VISIT 7	09JAN2017	9:05	3	Double Read
					VISIT 8	08JAN2018	9:27	2	Double Read
					VISIT 11	11JAN2021	9:15	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24	N	Double Read
					VISIT 6	27JUN2016	9:01	N	Double Read
					VISIT 7	09JAN2017	9:05	N	Double Read
					VISIT 8	08JAN2018	9:27	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0914 Age=35 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 11	11JAN2021	9:15	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24	N	Double Read
					VISIT 6	27JUN2016	9:01	N	Double Read
					VISIT 7	09JAN2017	9:05	N	Double Read
					VISIT 8	08JAN2018	9:27	N	Double Read
					VISIT 11	11JAN2021	9:15	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	04JAN2016	13:46	Y	Double Read
					VISIT 4	15FEB2016	9:24	N	Double Read
					VISIT 6	27JUN2016	9:01	N	Double Read
					VISIT 7	09JAN2017	9:05	N	Double Read
					VISIT 8	08JAN2018	9:27	N	Double Read
					VISIT 11	11JAN2021	9:15	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24	N	Double Read
					VISIT 6	27JUN2016	9:01	N	Double Read
					VISIT 7	09JAN2017	9:05	N	Double Read
					VISIT 8	08JAN2018	9:27	N	Double Read
					VISIT 11	11JAN2021	9:15	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24	N	Double Read
					VISIT 6	27JUN2016	9:01	N	Double Read
					VISIT 7	09JAN2017	9:05	N	Double Read
					VISIT 8	08JAN2018	9:27	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0914 Age=35 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 11	11JAN2021	9:15	N	Double Read
Fracture	5_S		General		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24	N	Double Read
					VISIT 6	27JUN2016	9:01	N	Double Read
					VISIT 7	09JAN2017	9:05	N	Double Read
					VISIT 8	08JAN2018	9:27	N	Double Read
					VISIT 11	11JAN2021	9:15	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	04JAN2016	13:46	13.92	Double Read
					VISIT 4	15FEB2016	9:24	14.525	Double Read
					VISIT 6	27JUN2016	9:01	13.865	Double Read
					VISIT 7	09JAN2017	9:05	13.83	Double Read
					VISIT 8	08JAN2018	9:27	13.16	Double Read
					VISIT 11	11JAN2021	9:15	11.76	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	04JAN2016	13:46	13.455	Double Read
					VISIT 4	15FEB2016	9:24	14.08	Double Read
					VISIT 6	27JUN2016	9:01	13.775	Double Read
					VISIT 7	09JAN2017	9:05	13.765	Double Read
					VISIT 8	08JAN2018	9:27	13.87	Double Read
					VISIT 11	11JAN2021	9:15	13.575	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0914 Age=35 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	04JAN2016	13:46	8.50013	Double Read
					VISIT 4	15FEB2016	9:24	8.69308	Double Read
					VISIT 6	27JUN2016	9:01	8.12728	Double Read
					VISIT 7	09JAN2017	9:05	7.84491	Double Read
					VISIT 8	08JAN2018	9:27	9.468055	Double Read
					VISIT 11	11JAN2021	9:15	8.365835	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	04JAN2016	13:46	10.55607	Double Read
					VISIT 4	15FEB2016	9:24	10.9666	Double Read
					VISIT 6	27JUN2016	9:01	11.067	Double Read
					VISIT 7	09JAN2017	9:05	10.99995	Double Read
					VISIT 8	08JAN2018	9:27	11.6294	Double Read
					VISIT 11	11JAN2021	9:15	11.38085	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24	N	Double Read
					VISIT 6	27JUN2016	9:01	N	Double Read
					VISIT 7	09JAN2017	9:05	N	Double Read
					VISIT 8	08JAN2018	9:27	N	Double Read
					VISIT 11	11JAN2021	9:15	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0914 Age=35 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24	N	Double Read
					VISIT 6	27JUN2016	9:01	N	Double Read
					VISIT 7	09JAN2017	9:05	N	Double Read
					VISIT 8	08JAN2018	9:27	N	Double Read
					VISIT 11	11JAN2021	9:15	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24	N	Double Read
					VISIT 6	27JUN2016	9:01	N	Double Read
					VISIT 7	09JAN2017	9:05	N	Double Read
					VISIT 8	08JAN2018	9:27	N	Double Read
					VISIT 11	11JAN2021	9:15	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24	N	Double Read
					VISIT 6	27JUN2016	9:01	N	Double Read
					VISIT 7	09JAN2017	9:05	N	Double Read
					VISIT 8	08JAN2018	9:27	N	Double Read
					VISIT 11	11JAN2021	9:15	N	Double Read
Normal lordotic LS	5_S		General		Baseline	04JAN2016	13:46	Y	Double Read
					VISIT 4	15FEB2016	9:24	Y	Double Read
					VISIT 6	27JUN2016	9:01	Y	Double Read
					VISIT 7	09JAN2017	9:05	Y	Double Read
					VISIT 8	08JAN2018	9:27	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0914 Age=35 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	5_S		General		VISIT 11	11JAN2021	9:15	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	04JAN2016	13:46	0	Double Read
					VISIT 4	15FEB2016	9:24	0	Double Read
					VISIT 6	27JUN2016	9:01	0	Double Read
					VISIT 7	09JAN2017	9:05	0	Double Read
					VISIT 8	08JAN2018	9:27	0	Double Read
					VISIT 11	11JAN2021	9:15	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04JAN2016	13:46	0	Double Read
					VISIT 4	15FEB2016	9:24	0	Double Read
					VISIT 6	27JUN2016	9:01	0	Double Read
					VISIT 7	09JAN2017	9:05	0	Double Read
					VISIT 8	08JAN2018	9:27	0	Double Read
					VISIT 11	11JAN2021	9:15	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24	N	Double Read
					VISIT 6	27JUN2016	9:01	N	Double Read
					VISIT 7	09JAN2017	9:05	N	Double Read
					VISIT 8	08JAN2018	9:27	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0914 Age=35 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 11	11JAN2021	9:15	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24	N	Double Read
					VISIT 6	27JUN2016	9:01	N	Double Read
					VISIT 7	09JAN2017	9:05	N	Double Read
					VISIT 8	08JAN2018	9:27	N	Double Read
					VISIT 11	11JAN2021	9:15	N	Double Read
Relevant scoliosis	5_S		General		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24	N	Double Read
					VISIT 6	27JUN2016	9:01	N	Double Read
					VISIT 7	09JAN2017	9:05	N	Double Read
					VISIT 8	08JAN2018	9:27	N	Double Read
					VISIT 11	11JAN2021	9:15	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24	N	Double Read
					VISIT 6	27JUN2016	9:01	N	Double Read
					VISIT 7	09JAN2017	9:05	N	Double Read
					VISIT 8	08JAN2018	9:27	N	Double Read
					VISIT 11	11JAN2021	9:15	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04JAN2016	13:46	N	Double Read
					VISIT 4	15FEB2016	9:24	N	Double Read
					VISIT 6	27JUN2016	9:01	N	Double Read
					VISIT 7	09JAN2017	9:05	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0914 Age=35 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	08JAN2018	9:27	N	Double Read
					VISIT 11	11JAN2021	9:15	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	04JAN2016	13:46	59.05152	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0914 Age=35 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 4	15FEB2016	9:24	72.11616	Double Read
					VISIT 6	27JUN2016	9:01	60.28944	Double Read
					VISIT 7	09JAN2017	9:05	61.35392	Double Read
					VISIT 8	08JAN2018	9:27	65.688	Double Read
					VISIT 11	11JAN2021	9:15	78.54208	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	04JAN2016	13:46	79.19696	Double Read
					VISIT 4	15FEB2016	9:24	80.0464	Double Read
					VISIT 6	27JUN2016	9:01	74.6696	Double Read
					VISIT 7	09JAN2017	9:05	80.23584	Double Read
					VISIT 8	08JAN2018	9:27	76.49152	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	11JAN2021	9:15	73.99504	Double Read
					Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0914 Age=35 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0914 Age=35 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	04JAN2016	13:46	lower	Double Read
					VISIT 4	15FEB2016	9:24	lower	Double Read
					VISIT 6	27JUN2016	9:01	lower	Double Read
					VISIT 7	09JAN2017	9:05	lower	Double Read
					VISIT 8	08JAN2018	9:27	lower	Double Read
					VISIT 11	11JAN2021	9:15	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0914 Age=35 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0914 Age=35 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	04JAN2016	13:46	10.8744419908	Double Read
					VISIT 4	15FEB2016	9:24	10.6015355869	Double Read
					VISIT 6	27JUN2016	9:01	6.91353830474	Double Read
					VISIT 7	09JAN2017	9:05	9.44080856124	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0914 Age=35 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	08JAN2018	9:27	7.69911330049	Double Read
					VISIT 11	11JAN2021	9:15	8.9774078478	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	04JAN2016	13:46	6.73800577544	Double Read
					VISIT 4	15FEB2016	9:24	8.74566332598	Double Read
					VISIT 6	27JUN2016	9:01	6.72129777476	Double Read
					VISIT 7	09JAN2017	9:05	11.1948156956	Double Read
					VISIT 8	08JAN2018	9:27	8.05163920503	Double Read
					VISIT 11	11JAN2021	9:15	10.1744250043	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0914 Age=35 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	04JAN2016	13:46	10592.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0914 Age=35 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 4	15FEB2016	9:24	12718.0	Double Read
					VISIT 6	27JUN2016	9:01	11882.0	Double Read
					VISIT 7	09JAN2017	9:05	11637.5	Double Read
					VISIT 8	08JAN2018	9:27	11398.0	Double Read
					VISIT 11	11JAN2021	9:15	10442.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	04JAN2016	13:46	15383.0	Double Read
					VISIT 4	15FEB2016	9:24	16939.5	Double Read
					VISIT 6	27JUN2016	9:01	16947.5	Double Read
					VISIT 7	09JAN2017	9:05	17442.0	Double Read
					VISIT 8	08JAN2018	9:27	17003.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	04JAN2016	13:46		Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15	16992.5	Double Read
					VISIT 4	15FEB2016	9:24		Double Read
					VISIT 6	27JUN2016	9:01		Double Read
					VISIT 7	09JAN2017	9:05		Double Read
					VISIT 8	08JAN2018	9:27		Double Read
					VISIT 11	11JAN2021	9:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	05JAN2016	15:10	2	Double Read
					VISIT 3A	23MAR2016	10:51	2	Double Read
					VISIT 4	02MAY2016	9:03	2	Double Read
					VISIT 6	26SEP2016	9:15	2	Double Read
					VISIT 7	03APR2017	10:14	2	Double Read
					VISIT 8	09APR2018	9:34	2	Double Read
					VISIT 11	22FEB2021	8:38	2	Double Read
					UNSCHEDULED	21DEC2016	13:26	2	Double Read
					UNSCHEDULED	23JUL2020	7:35	2	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	05JAN2016	15:10	3	Double Read
					VISIT 3A	23MAR2016	10:51	3	Double Read
					VISIT 4	02MAY2016	9:03	3	Double Read
					VISIT 6	26SEP2016	9:15	3	Double Read
					VISIT 7	03APR2017	10:14	3	Double Read
					VISIT 8	09APR2018	9:34	3	Double Read
					VISIT 11	22FEB2021	8:38	3	Double Read
					UNSCHEDULED	21DEC2016	13:26	3	Double Read
					UNSCHEDULED	23JUL2020	7:35	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	05JAN2016	15:10	3	Double Read
					VISIT 3A	23MAR2016	10:51	3	Double Read
					VISIT 4	02MAY2016	9:03	3	Double Read
					VISIT 6	26SEP2016	9:15	3	Double Read
					VISIT 7	03APR2017	10:14	3	Double Read
					VISIT 8	09APR2018	9:34	3	Double Read
					VISIT 11	22FEB2021	8:38	3	Double Read
					UNSCHEDULED	21DEC2016	13:26	3	Double Read
					UNSCHEDULED	23JUL2020	7:35	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		VISIT 7	03APR2017	10:14	N	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
					UNSCHEDULED	23JUL2020	7:35	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read
					VISIT 7	03APR2017	10:14	N	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
					UNSCHEDULED	23JUL2020	7:35	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read
					VISIT 7	03APR2017	10:14	N	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
					UNSCHEDULED	23JUL2020	7:35	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read
					VISIT 7	03APR2017	10:14	N	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
					UNSCHEDULED	23JUL2020	7:35	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	05JAN2016	15:10	Y	Double Read
					VISIT 3A	23MAR2016	10:51	Y	Double Read
					VISIT 4	02MAY2016	9:03	Y	Double Read
					VISIT 6	26SEP2016	9:15	Y	Double Read
					VISIT 7	03APR2017	10:14	Y	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
					UNSCHEDULED	23JUL2020	7:35	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read
					VISIT 7	03APR2017	10:14	N	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
					UNSCHEDULED	23JUL2020	7:35	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read
					VISIT 7	03APR2017	10:14	N	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
					UNSCHEDULED	23JUL2020	7:35	N	Double Read
Fracture	4_5		General		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read
					VISIT 7	03APR2017	10:14	N	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Fracture	4_5		General		UNSCHEDULED UNSCHEDULED	21DEC2016 23JUL2020	13:26 7:35	N N	Double Read Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline VISIT 3A VISIT 4 VISIT 6 VISIT 7 VISIT 8 VISIT 11 UNSCHEDULED UNSCHEDULED	05JAN2016 23MAR2016 02MAY2016 26SEP2016 03APR2017 09APR2018 22FEB2021 21DEC2016 23JUL2020	15:10 10:51 9:03 9:15 10:14 9:34 8:38 13:26 7:35	11.045 11.52 14.125 11.95 11.28 11.805 12.405 11.68 12.585	Double Read Double Read Double Read Double Read Double Read Double Read Double Read Double Read Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline VISIT 3A VISIT 4 VISIT 6 VISIT 7 VISIT 8 VISIT 11 UNSCHEDULED UNSCHEDULED	05JAN2016 23MAR2016 02MAY2016 26SEP2016 03APR2017 09APR2018 22FEB2021 21DEC2016 23JUL2020	15:10 10:51 9:03 9:15 10:14 9:34 8:38 13:26 7:35	13.75 15.38 16.945 16.16 15.45 15.36 15.665 16.275 16.185	Double Read Double Read Double Read Double Read Double Read Double Read Double Read Double Read Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline VISIT 3A VISIT 4 VISIT 6 VISIT 7 VISIT 8 VISIT 11 UNSCHEDULED UNSCHEDULED	05JAN2016 23MAR2016 02MAY2016 26SEP2016 03APR2017 09APR2018 22FEB2021 21DEC2016 23JUL2020	15:10 10:51 9:03 9:15 10:14 9:34 8:38 13:26 7:35	14.315 15.23 16.57 14.965 14.8 16.1 15.12 15.12 14.985	Double Read Double Read Double Read Double Read Double Read Double Read Double Read Double Read Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	05JAN2016	15:10	9.166355	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	VISIT 3A	23MAR2016	10:51	8.855805	Double Read
					VISIT 4	02MAY2016	9:03	8.72294	Double Read
					VISIT 6	26SEP2016	9:15	9.391895	Double Read
					VISIT 7	03APR2017	10:14	9.368665	Double Read
					VISIT 8	09APR2018	9:34	9.29419	Double Read
					VISIT 11	22FEB2021	8:38	9.660205	Double Read
					UNSCHEDULED	21DEC2016	13:26	9.10445	Double Read
					UNSCHEDULED	23JUL2020	7:35	9.54426	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	05JAN2016	15:10	9.38164	Double Read
					VISIT 3A	23MAR2016	10:51	9.26576	Double Read
					VISIT 4	02MAY2016	9:03	8.61434	Double Read
					VISIT 6	26SEP2016	9:15	9.8676	Double Read
					VISIT 7	03APR2017	10:14	9.04673	Double Read
					VISIT 8	09APR2018	9:34	9.54533	Double Read
					VISIT 11	22FEB2021	8:38	9.255895	Double Read
					UNSCHEDULED	21DEC2016	13:26	9.776385	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	05JAN2016	15:10	9.79391	Double Read
					VISIT 3A	23MAR2016	10:51	9.66289	Double Read
					VISIT 4	02MAY2016	9:03	10.3635	Double Read
					VISIT 6	26SEP2016	9:15	9.751925	Double Read
					VISIT 7	03APR2017	10:14	9.48803	Double Read
					VISIT 8	09APR2018	9:34	10.47495	Double Read
					VISIT 11	22FEB2021	8:38	10.20918	Double Read
					UNSCHEDULED	21DEC2016	13:26	8.987085	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		VISIT 7	03APR2017	10:14	N	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
					UNSCHEDULED	23JUL2020	7:35	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read
					VISIT 7	03APR2017	10:14	N	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
					UNSCHEDULED	23JUL2020	7:35	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read
					VISIT 7	03APR2017	10:14	N	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
					UNSCHEDULED	23JUL2020	7:35	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read
					VISIT 7	03APR2017	10:14	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
					UNSCHEDULED	23JUL2020	7:35	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read
					VISIT 7	03APR2017	10:14	N	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read
					VISIT 7	03APR2017	10:14	N	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
Normal lordotic LS	4_5		General		Baseline	05JAN2016	15:10	Y	Double Read
					VISIT 3A	23MAR2016	10:51	Y	Double Read
					VISIT 4	02MAY2016	9:03	Y	Double Read
					VISIT 6	26SEP2016	9:15	Y	Double Read
					VISIT 7	03APR2017	10:14	Y	Double Read
					VISIT 8	09APR2018	9:34	Y	Double Read
					VISIT 11	22FEB2021	8:38	Y	Double Read
					UNSCHEDULED	21DEC2016	13:26	Y	Double Read
					UNSCHEDULED	23JUL2020	7:35	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	05JAN2016	15:10	0	Double Read
					VISIT 3A	23MAR2016	10:51	0	Double Read
					VISIT 4	02MAY2016	9:03	0	Double Read
					VISIT 6	26SEP2016	9:15	0	Double Read
					VISIT 7	03APR2017	10:14	0	Double Read
					VISIT 8	09APR2018	9:34	0	Double Read
					VISIT 11	22FEB2021	8:38	0	Double Read
					UNSCHEDULED	21DEC2016	13:26	0	Double Read
					UNSCHEDULED	23JUL2020	7:35	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	05JAN2016	15:10	0	Double Read
					VISIT 3A	23MAR2016	10:51	0	Double Read
					VISIT 4	02MAY2016	9:03	0	Double Read
					VISIT 6	26SEP2016	9:15	2	Double Read
					VISIT 7	03APR2017	10:14	0	Double Read
					VISIT 8	09APR2018	9:34	0	Double Read
					VISIT 11	22FEB2021	8:38	0	Double Read
					UNSCHEDULED	21DEC2016	13:26	2	Double Read
					UNSCHEDULED	23JUL2020	7:35	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	05JAN2016	15:10	0	Double Read
					VISIT 3A	23MAR2016	10:51	0	Double Read
					VISIT 4	02MAY2016	9:03	0	Double Read
					VISIT 6	26SEP2016	9:15	0	Double Read
					VISIT 7	03APR2017	10:14	0	Double Read
					VISIT 8	09APR2018	9:34	0	Double Read
					VISIT 11	22FEB2021	8:38	0	Double Read
					UNSCHEDULED	21DEC2016	13:26	0	Double Read
					UNSCHEDULED	23JUL2020	7:35	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read
					VISIT 7	03APR2017	10:14	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
					UNSCHEDULED	23JUL2020	7:35	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read
					VISIT 7	03APR2017	10:14	N	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read
					VISIT 7	03APR2017	10:14	N	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
Relevant scoliosis	4_5		General		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read
					VISIT 7	03APR2017	10:14	N	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	05JAN2016	15:10	N	Double Read
					UNSCHEDULED	23JUL2020	7:35	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read
					VISIT 7	03APR2017	10:14	N	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
					UNSCHEDULED	23JUL2020	7:35	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read
					VISIT 7	03APR2017	10:14	N	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	05JAN2016	15:10	N	Double Read
					VISIT 3A	23MAR2016	10:51	N	Double Read
					VISIT 4	02MAY2016	9:03	N	Double Read
					VISIT 6	26SEP2016	9:15	N	Double Read
					VISIT 7	03APR2017	10:14	N	Double Read
					VISIT 8	09APR2018	9:34	N	Double Read
					VISIT 11	22FEB2021	8:38	N	Double Read
					UNSCHEDULED	21DEC2016	13:26	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	05JAN2016	15:10	94.42592	Double Read
					VISIT 3A	23MAR2016	10:51	95.11328	Double Read
					VISIT 4	02MAY2016	9:03	98.14048	Double Read
					VISIT 6	26SEP2016	9:15	85.49264	Double Read
					VISIT 7	03APR2017	10:14	95.92864	Double Read
					VISIT 8	09APR2018	9:34	91.42112	Double Read
					VISIT 11	22FEB2021	8:38	96.54976	Double Read
					UNSCHEDULED	21DEC2016	13:26	80.04352	Double Read
					UNSCHEDULED	23JUL2020	7:35	88.36512	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	05JAN2016	15:10	58.2248	Double Read
					VISIT 3A	23MAR2016	10:51	58.52176	Double Read
					VISIT 4	02MAY2016	9:03	63.12112	Double Read
					VISIT 6	26SEP2016	9:15	66.3056	Double Read
					VISIT 7	03APR2017	10:14	65.27824	Double Read
					VISIT 8	09APR2018	9:34	67.3696	Double Read
					VISIT 11	22FEB2021	8:38	59.27504	Double Read
					UNSCHEDULED	21DEC2016	13:26	65.35888	Double Read
					UNSCHEDULED	23JUL2020	7:35	65.25664	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	05JAN2016	15:10	71.33136	Double Read
					VISIT 3A	23MAR2016	10:51	65.97136	Double Read
					VISIT 4	02MAY2016	9:03	66.6448	Double Read
					VISIT 6	26SEP2016	9:15	72.44016	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	VISIT 7	03APR2017	10:14	66.40832	Double Read
					VISIT 8	09APR2018	9:34	64.83936	Double Read
					VISIT 11	22FEB2021	8:38	71.02512	Double Read
					UNSCHEDULED	21DEC2016	13:26	68.01168	Double Read
					UNSCHEDULED	23JUL2020	7:35	71.67792	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	05JAN2016	15:10	lower	Double Read
					VISIT 3A	23MAR2016	10:51	lower	Double Read
					VISIT 4	02MAY2016	9:03	lower	Double Read
					VISIT 6	26SEP2016	9:15	lower	Double Read
					VISIT 7	03APR2017	10:14	lower	Double Read
					VISIT 8	09APR2018	9:34	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		VISIT 11	22FEB2021	8:38	lower	Double Read
					UNSCHEDULED	21DEC2016	13:26	lower	Double Read
					UNSCHEDULED	23JUL2020	7:35	lower	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	05JAN2016	15:10	lower	Double Read
					VISIT 3A	23MAR2016	10:51	equal	Double Read
					VISIT 4	02MAY2016	9:03	equal	Double Read
					VISIT 6	26SEP2016	9:15	lower	Double Read
					VISIT 7	03APR2017	10:14	lower	Double Read
					VISIT 8	09APR2018	9:34	equal	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		VISIT 11	22FEB2021	8:38	equal	Double Read
					UNSCHEDULED	21DEC2016	13:26	lower	Double Read
					UNSCHEDULED	23JUL2020	7:35	equal	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		UNSCHEDULED	23JUL2020	7:35		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	05JAN2016	15:10	3.4417462204	Double Read
					VISIT 3A	23MAR2016	10:51	4.9714081875	Double Read
					VISIT 4	02MAY2016	9:03	4.2086291829	Double Read
					VISIT 6	26SEP2016	9:15	6.5718158654	Double Read
					VISIT 7	03APR2017	10:14	8.8330219126	Double Read
					VISIT 8	09APR2018	9:34	9.4181144895	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	VISIT 11	22FEB2021	8:38	7.31231527096	Double Read
					UNSCHEDULED	21DEC2016	13:26	7.66822490235	Double Read
					UNSCHEDULED	23JUL2020	7:35	8.66315610668	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	05JAN2016	15:10	5.97354170205	Double Read
					VISIT 3A	23MAR2016	10:51	10.0578494989	Double Read
					VISIT 4	02MAY2016	9:03	10.0994666214	Double Read
					VISIT 6	26SEP2016	9:15	7.18920332937	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 7	03APR2017	10:14	11.5100594531	Double Read
					VISIT 8	09APR2018	9:34	4.36050959742	Double Read
					VISIT 11	22FEB2021	8:38	9.12561236621	Double Read
					UNSCHEDULED	21DEC2016	13:26	10.8006319008	Double Read
					UNSCHEDULED	23JUL2020	7:35	13.9042636317	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	05JAN2016	15:10	12.5415253949	Double Read
					VISIT 3A	23MAR2016	10:51	9.55130966537	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	VISIT 4	02MAY2016	9:03	7.26540512994	Double Read
					VISIT 6	26SEP2016	9:15	9.96384576183	Double Read
					VISIT 7	03APR2017	10:14	11.4647324613	Double Read
					VISIT 8	09APR2018	9:34	9.7341192458	Double Read
					VISIT 11	22FEB2021	8:38	5.64871071853	Double Read
					UNSCHEDULED	21DEC2016	13:26	11.4376286733	Double Read
					UNSCHEDULED	23JUL2020	7:35	6.65873959572	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	05JAN2016	15:10	10739.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	VISIT 3A	23MAR2016	10:51	10995.0	Double Read
					VISIT 4	02MAY2016	9:03	12541.5	Double Read
					VISIT 6	26SEP2016	9:15	13124.5	Double Read
					VISIT 7	03APR2017	10:14	11319.5	Double Read
					VISIT 8	09APR2018	9:34	11879.5	Double Read
					VISIT 11	22FEB2021	8:38	12971.0	Double Read
					UNSCHEDULED	21DEC2016	13:26	11628.5	Double Read
					UNSCHEDULED	23JUL2020	7:35	12818.0	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	05JAN2016	15:10	16490.5	Double Read
					VISIT 3A	23MAR2016	10:51	16201.0	Double Read
					VISIT 4	02MAY2016	9:03	19744.5	Double Read
					VISIT 6	26SEP2016	9:15	19216.5	Double Read
					VISIT 7	03APR2017	10:14	17903.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 8	09APR2018	9:34	18316.0	Double Read
					VISIT 11	22FEB2021	8:38	20182.0	Double Read
					UNSCHEDULED	21DEC2016	13:26	19174.0	Double Read
					UNSCHEDULED	23JUL2020	7:35	19999.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	05JAN2016	15:10	20109.5	Double Read
					VISIT 3A	23MAR2016	10:51	19368.5	Double Read
					VISIT 4	02MAY2016	9:03	21969.5	Double Read
					VISIT 6	26SEP2016	9:15	19972.5	Double Read
					VISIT 7	03APR2017	10:14	19953.5	Double Read
					VISIT 8	09APR2018	9:34	20795.0	Double Read
					VISIT 11	22FEB2021	8:38	20386.0	Double Read
					UNSCHEDULED	21DEC2016	13:26	21111.5	Double Read
					UNSCHEDULED	23JUL2020	7:35	20904.0	Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0915 Age=48 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	05JAN2016	15:10		Double Read
					VISIT 3A	23MAR2016	10:51		Double Read
					VISIT 4	02MAY2016	9:03		Double Read
					VISIT 6	26SEP2016	9:15		Double Read
					VISIT 7	03APR2017	10:14		Double Read
					VISIT 8	09APR2018	9:34		Double Read
					VISIT 11	22FEB2021	8:38		Double Read
					UNSCHEDULED	21DEC2016	13:26		Double Read
					UNSCHEDULED	23JUL2020	7:35		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0916 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43	2	Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	22FEB2016	13:13	3	Double Read
					VISIT 4	06APR2016	10:43	3	Double Read
					VISIT 6	29AUG2016	9:16	3	Double Read
					VISIT 7	20FEB2017	9:17	3	Double Read
					VISIT 8	26FEB2018	9:24	3	Double Read
					VISIT 11	01MAR2021	8:55	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22FEB2016	13:13	2	Double Read
					VISIT 4	06APR2016	10:43	2	Double Read
					VISIT 6	29AUG2016	9:16	2	Double Read
					VISIT 7	20FEB2017	9:17	2	Double Read
					VISIT 8	26FEB2018	9:24	2	Double Read
					VISIT 11	01MAR2021	8:55	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	22FEB2016	13:13	N	Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16	N	Double Read
					VISIT 7	20FEB2017	9:17	N	Double Read
					VISIT 8	26FEB2018	9:24	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0916 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 11	01MAR2021	8:55	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22FEB2016	13:13	N	Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16	N	Double Read
					VISIT 7	20FEB2017	9:17	N	Double Read
					VISIT 8	26FEB2018	9:24	N	Double Read
					VISIT 11	01MAR2021	8:55	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	22FEB2016	13:13	Y	Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16	N	Double Read
					VISIT 7	20FEB2017	9:17	N	Double Read
					VISIT 8	26FEB2018	9:24	N	Double Read
					VISIT 11	01MAR2021	8:55	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22FEB2016	13:13	N	Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16	N	Double Read
					VISIT 7	20FEB2017	9:17	N	Double Read
					VISIT 8	26FEB2018	9:24	N	Double Read
					VISIT 11	01MAR2021	8:55	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	22FEB2016	13:13	N	Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16	N	Double Read
					VISIT 7	20FEB2017	9:17	N	Double Read
					VISIT 8	26FEB2018	9:24	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0916 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 11	01MAR2021	8:55	N	Double Read
Fracture	5_S		General		Baseline	22FEB2016	13:13	N	Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16	N	Double Read
					VISIT 7	20FEB2017	9:17	N	Double Read
					VISIT 8	26FEB2018	9:24	N	Double Read
					VISIT 11	01MAR2021	8:55	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43	7.99	Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22FEB2016	13:13	14.25	Double Read
					VISIT 4	06APR2016	10:43	15.5	Double Read
					VISIT 6	29AUG2016	9:16	15.35	Double Read
					VISIT 7	20FEB2017	9:17	15.52	Double Read
					VISIT 8	26FEB2018	9:24	15.77	Double Read
					VISIT 11	01MAR2021	8:55	15.58	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22FEB2016	13:13	17.85	Double Read
					VISIT 4	06APR2016	10:43	19.5	Double Read
					VISIT 6	29AUG2016	9:16	17.43	Double Read
					VISIT 7	20FEB2017	9:17	17.91	Double Read
					VISIT 8	26FEB2018	9:24	18.09	Double Read
					VISIT 11	01MAR2021	8:55	18.01	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43	6.789435	Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0916 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22FEB2016	13:13	10.2153	Double Read
					VISIT 4	06APR2016	10:43	9.254415	Double Read
					VISIT 6	29AUG2016	9:16	9.42372	Double Read
					VISIT 7	20FEB2017	9:17	8.867225	Double Read
					VISIT 8	26FEB2018	9:24	9.41123	Double Read
					VISIT 11	01MAR2021	8:55	8.95196	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22FEB2016	13:13	12.91995	Double Read
					VISIT 4	06APR2016	10:43	13.21045	Double Read
					VISIT 6	29AUG2016	9:16	13.4594	Double Read
					VISIT 7	20FEB2017	9:17	12.49755	Double Read
					VISIT 8	26FEB2018	9:24	12.07615	Double Read
					VISIT 11	01MAR2021	8:55	12.201	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	22FEB2016	13:13	N	Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16	N	Double Read
					VISIT 7	20FEB2017	9:17	N	Double Read
					VISIT 8	26FEB2018	9:24	N	Double Read
					VISIT 11	01MAR2021	8:55	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0916 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22FEB2016	13:13	N	Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16	N	Double Read
					VISIT 7	20FEB2017	9:17	N	Double Read
					VISIT 8	26FEB2018	9:24	N	Double Read
					VISIT 11	01MAR2021	8:55	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	22FEB2016	13:13	N	Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16	N	Double Read
					VISIT 7	20FEB2017	9:17	N	Double Read
					VISIT 8	26FEB2018	9:24	N	Double Read
					VISIT 11	01MAR2021	8:55	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22FEB2016	13:13	N	Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16	N	Double Read
					VISIT 7	20FEB2017	9:17	N	Double Read
					VISIT 8	26FEB2018	9:24	N	Double Read
					VISIT 11	01MAR2021	8:55	N	Double Read
Normal lordotic LS	5_S		General		Baseline	22FEB2016	13:13	Y	Double Read
					VISIT 4	06APR2016	10:43	Y	Double Read
					VISIT 6	29AUG2016	9:16	Y	Double Read
					VISIT 7	20FEB2017	9:17	Y	Double Read
					VISIT 8	26FEB2018	9:24	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0916 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	5_S		General		VISIT 11	01MAR2021	8:55	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43	0	Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	22FEB2016	13:13	0	Double Read
					VISIT 4	06APR2016	10:43	0	Double Read
					VISIT 6	29AUG2016	9:16	0	Double Read
					VISIT 7	20FEB2017	9:17	0	Double Read
					VISIT 8	26FEB2018	9:24	0	Double Read
					VISIT 11	01MAR2021	8:55	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22FEB2016	13:13	0	Double Read
					VISIT 4	06APR2016	10:43	0	Double Read
					VISIT 6	29AUG2016	9:16	0	Double Read
					VISIT 7	20FEB2017	9:17	0	Double Read
					VISIT 8	26FEB2018	9:24	0	Double Read
					VISIT 11	01MAR2021	8:55	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	22FEB2016	13:13	N	Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16	N	Double Read
					VISIT 7	20FEB2017	9:17	N	Double Read
					VISIT 8	26FEB2018	9:24	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0916 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 11	01MAR2021	8:55	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22FEB2016	13:13	N	Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16	N	Double Read
					VISIT 7	20FEB2017	9:17	N	Double Read
					VISIT 8	26FEB2018	9:24	N	Double Read
					VISIT 11	01MAR2021	8:55	N	Double Read
Relevant scoliosis	5_S		General		Baseline	22FEB2016	13:13	N	Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16	N	Double Read
					VISIT 7	20FEB2017	9:17	N	Double Read
					VISIT 8	26FEB2018	9:24	N	Double Read
					VISIT 11	01MAR2021	8:55	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	22FEB2016	13:13	N	Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16	N	Double Read
					VISIT 7	20FEB2017	9:17	N	Double Read
					VISIT 8	26FEB2018	9:24	N	Double Read
					VISIT 11	01MAR2021	8:55	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	22FEB2016	13:13	N	Double Read
					VISIT 4	06APR2016	10:43	N	Double Read
					VISIT 6	29AUG2016	9:16	N	Double Read
					VISIT 7	20FEB2017	9:17	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0916 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	26FEB2018	9:24	N	Double Read
					VISIT 11	01MAR2021	8:55	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43	81.136	Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22FEB2016	13:13	64.80112	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0916 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 4	06APR2016	10:43	64.51984	Double Read
					VISIT 6	29AUG2016	9:16	66.74592	Double Read
					VISIT 7	20FEB2017	9:17	65.60224	Double Read
					VISIT 8	26FEB2018	9:24	63.736	Double Read
					VISIT 11	01MAR2021	8:55	62.91168	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22FEB2016	13:13	94.76448	Double Read
					VISIT 4	06APR2016	10:43	88.09856	Double Read
					VISIT 6	29AUG2016	9:16	85.22064	Double Read
					VISIT 7	20FEB2017	9:17	89.48768	Double Read
					VISIT 8	26FEB2018	9:24	87.02048	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55	77.19872	Double Read
					VISIT 11	01MAR2021	8:55		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
					VISIT 11	01MAR2021	8:55		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0916 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0916 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	22FEB2016	13:13	lower	Double Read
					VISIT 4	06APR2016	10:43	lower	Double Read
					VISIT 6	29AUG2016	9:16	lower	Double Read
					VISIT 7	20FEB2017	9:17	lower	Double Read
					VISIT 8	26FEB2018	9:24	lower	Double Read
					VISIT 11	01MAR2021	8:55	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0916 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0916 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43	4.71984372346	Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22FEB2016	13:13	15.0972651606	Double Read
					VISIT 4	06APR2016	10:43	8.16689655172	Double Read
					VISIT 6	29AUG2016	9:16	9.05007643962	Double Read
					VISIT 7	20FEB2017	9:17	10.8228775268	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0916 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	26FEB2018	9:24	11.4857618481	Double Read
					VISIT 11	01MAR2021	8:55	7.47409546458	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22FEB2016	13:13	8.16848649567	Double Read
					VISIT 4	06APR2016	10:43	15.5370817054	Double Read
					VISIT 6	29AUG2016	9:16	7.65339901478	Double Read
					VISIT 7	20FEB2017	9:17	9.02553422796	Double Read
					VISIT 8	26FEB2018	9:24	11.4861627315	Double Read
					VISIT 11	01MAR2021	8:55	15.6605401733	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0916 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43	3721.5	Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0916 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	22FEB2016	13:13	14198.0	Double Read
					VISIT 4	06APR2016	10:43	14718.0	Double Read
					VISIT 6	29AUG2016	9:16	15352.5	Double Read
					VISIT 7	20FEB2017	9:17	16410.5	Double Read
					VISIT 8	26FEB2018	9:24	14146.5	Double Read
					VISIT 11	01MAR2021	8:55	15162.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read
					VISIT 11	01MAR2021	8:55		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	22FEB2016	13:13	23875.5	Double Read
					VISIT 4	06APR2016	10:43	23637.5	Double Read
					VISIT 6	29AUG2016	9:16	24374.5	Double Read
					VISIT 7	20FEB2017	9:17	25857.5	Double Read
					VISIT 8	26FEB2018	9:24	22591.5	Double Read
					VISIT 11	01MAR2021	8:55	23133.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	22FEB2016	13:13		Double Read
					VISIT 4	06APR2016	10:43		Double Read
					VISIT 6	29AUG2016	9:16		Double Read
					VISIT 7	20FEB2017	9:17		Double Read
					VISIT 8	26FEB2018	9:24		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=09/0916 Age=57 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	01MAR2021	8:55		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S	4_5	Central Disc		Baseline	12JAN2015	12:27	3	Double Read
					VISIT 3A	30MAR2015	11:44	3	Double Read
					VISIT 4	11MAY2015	9:51	3	Double Read
					VISIT 6	09OCT2015	9:25	3	Double Read
					VISIT 7	08APR2016	9:54	3	Double Read
					VISIT 8	24JAN2017	10:51	3	Double Read
					VISIT 11	06MAR2020	11:09	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	12JAN2015	12:27	3	Double Read
					VISIT 3A	30MAR2015	11:44	3	Double Read
					VISIT 4	11MAY2015	9:51	3	Double Read
					VISIT 6	09OCT2015	9:25	3	Double Read
					VISIT 7	08APR2016	9:54	3	Double Read
					VISIT 8	24JAN2017	10:51	3	Double Read
					VISIT 11	06MAR2020	11:09	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S	4_5	Central Disc		Baseline	12JAN2015	12:27	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S	4_5	Central Disc		VISIT 3A	30MAR2015	11:44	N	Double Read
					VISIT 4	11MAY2015	9:51	N	Double Read
					VISIT 6	09OCT2015	9:25	N	Double Read
					VISIT 7	08APR2016	9:54	N	Double Read
					VISIT 8	24JAN2017	10:51	N	Double Read
					VISIT 11	06MAR2020	11:09	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	12JAN2015	12:27	N	Double Read
					VISIT 3A	30MAR2015	11:44	N	Double Read
					VISIT 4	11MAY2015	9:51	N	Double Read
					VISIT 6	09OCT2015	9:25	N	Double Read
					VISIT 7	08APR2016	9:54	N	Double Read
					VISIT 8	24JAN2017	10:51	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S	4_5	Caudal Disc		VISIT 11	06MAR2020	11:09	N	Double Read
					Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
Dorsal disc extrusion (Central Disc)	5_S	4_5	Central Disc		VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
					Baseline	12JAN2015	12:27	Y	Double Read
					VISIT 3A	30MAR2015	11:44	Y	Double Read
					VISIT 4	11MAY2015	9:51	Y	Double Read
					VISIT 6	09OCT2015	9:25	N	Double Read
Dorsal disc extrusion (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 7	08APR2016	9:54	Y	Double Read
					VISIT 8	24JAN2017	10:51	Y	Double Read
					VISIT 11	06MAR2020	11:09	N	Double Read
					Baseline	12JAN2015	12:27	N	Double Read
					VISIT 3A	30MAR2015	11:44	N	Double Read
					VISIT 4	11MAY2015	9:51	Y	Double Read
					VISIT 6	09OCT2015	9:25	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 7	08APR2016	9:54	Y	Double Read
					VISIT 8	24JAN2017	10:51	Y	Double Read
					VISIT 11	06MAR2020	11:09	Y	Double Read
Extradiscal fluid collection	5_S	4_5	General		Baseline	12JAN2015	12:27	N	Double Read
					VISIT 3A	30MAR2015	11:44	N	Double Read
					VISIT 4	11MAY2015	9:51	N	Double Read
					VISIT 6	09OCT2015	9:25	N	Double Read
					VISIT 7	08APR2016	9:54	N	Double Read
					VISIT 8	24JAN2017	10:51	N	Double Read
					VISIT 11	06MAR2020	11:09	N	Double Read
Fracture	5_S	4_5	General		Baseline	12JAN2015	12:27	N	Double Read
					VISIT 3A	30MAR2015	11:44	N	Double Read
					VISIT 4	11MAY2015	9:51	N	Double Read
					VISIT 6	09OCT2015	9:25	N	Double Read
					VISIT 7	08APR2016	9:54	N	Double Read
					VISIT 8	24JAN2017	10:51	N	Double Read
					VISIT 11	06MAR2020	11:09	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	12JAN2015	12:27	13.14	Double Read
					VISIT 3A	30MAR2015	11:44	15.51	Double Read
					VISIT 4	11MAY2015	9:51	14.305	Double Read
					VISIT 6	09OCT2015	9:25	14.82	Double Read
					VISIT 7	08APR2016	9:54	12.685	Double Read
					VISIT 8	24JAN2017	10:51	12.38	Double Read
					VISIT 11	06MAR2020	11:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	12JAN2015	12:27	13.735	Double Read
					VISIT 3A	30MAR2015	11:44	14.57	Double Read
					VISIT 4	11MAY2015	9:51	15.56	Double Read
					VISIT 6	09OCT2015	9:25	15.53	Double Read
					VISIT 7	08APR2016	9:54	14.9	Double Read
					VISIT 8	24JAN2017	10:51	13.93	Double Read
					VISIT 11	06MAR2020	11:09		Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	12JAN2015	12:27	9.32838	Double Read
					VISIT 3A	30MAR2015	11:44	9.84867	Double Read
					VISIT 4	11MAY2015	9:51	9.37464	Double Read
					VISIT 6	09OCT2015	9:25	8.84467	Double Read
					VISIT 7	08APR2016	9:54	8.756495	Double Read
					VISIT 8	24JAN2017	10:51	7.780235	Double Read
					VISIT 11	06MAR2020	11:09		Double Read
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	12JAN2015	12:27	10.26565	Double Read
					VISIT 3A	30MAR2015	11:44	11.1438	Double Read
					VISIT 4	11MAY2015	9:51	10.74905	Double Read
					VISIT 6	09OCT2015	9:25	10.73165	Double Read
					VISIT 7	08APR2016	9:54	10.2564	Double Read
					VISIT 8	24JAN2017	10:51	10.12395	Double Read
					VISIT 11	06MAR2020	11:09	10.058505	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S	4_5	Central Disc		Baseline	12JAN2015	12:27	N	Double Read
					VISIT 3A	30MAR2015	11:44	N	Double Read
					VISIT 4	11MAY2015	9:51	N	Double Read
					VISIT 6	09OCT2015	9:25	N	Double Read
					VISIT 7	08APR2016	9:54	N	Double Read
					VISIT 8	24JAN2017	10:51	N	Double Read
					VISIT 11	06MAR2020	11:09	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	12JAN2015	12:27	N	Double Read
					VISIT 3A	30MAR2015	11:44	N	Double Read
					VISIT 4	11MAY2015	9:51	N	Double Read
					VISIT 6	09OCT2015	9:25	N	Double Read
					VISIT 7	08APR2016	9:54	N	Double Read
					VISIT 8	24JAN2017	10:51	N	Double Read
					VISIT 11	06MAR2020	11:09	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S	4_5	Central Disc		Baseline	12JAN2015	12:27	N	Double Read
					VISIT 3A	30MAR2015	11:44	N	Double Read
					VISIT 4	11MAY2015	9:51	N	Double Read
					VISIT 6	09OCT2015	9:25	N	Double Read
					VISIT 7	08APR2016	9:54	N	Double Read
					VISIT 8	24JAN2017	10:51	N	Double Read
					VISIT 11	06MAR2020	11:09	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	12JAN2015	12:27	N	Double Read
					VISIT 3A	30MAR2015	11:44	N	Double Read
					VISIT 4	11MAY2015	9:51	N	Double Read
					VISIT 6	09OCT2015	9:25	N	Double Read
					VISIT 7	08APR2016	9:54	N	Double Read
					VISIT 8	24JAN2017	10:51	N	Double Read
					VISIT 11	06MAR2020	11:09	N	Double Read
Normal lordotic LS	5_S	4_5	General		Baseline	12JAN2015	12:27	Y	Double Read
					VISIT 3A	30MAR2015	11:44	Y	Double Read
					VISIT 4	11MAY2015	9:51	Y	Double Read
					VISIT 6	09OCT2015	9:25	Y	Double Read
					VISIT 7	08APR2016	9:54	Y	Double Read
					VISIT 8	24JAN2017	10:51	Y	Double Read
					VISIT 11	06MAR2020	11:09	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S	4_5	Central Disc		Baseline	12JAN2015	12:27	0	Double Read
					VISIT 3A	30MAR2015	11:44	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S	4_5	Central Disc		VISIT 4	11MAY2015	9:51	0	Double Read
					VISIT 6	09OCT2015	9:25	0	Double Read
					VISIT 7	08APR2016	9:54	1	Double Read
					VISIT 8	24JAN2017	10:51	1	Double Read
					VISIT 11	06MAR2020	11:09	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	12JAN2015	12:27	0	Double Read
					VISIT 3A	30MAR2015	11:44	0	Double Read
					VISIT 4	11MAY2015	9:51	0	Double Read
					VISIT 6	09OCT2015	9:25	0	Double Read
					VISIT 7	08APR2016	9:54	0	Double Read
					VISIT 8	24JAN2017	10:51	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S	4_5	Caudal Disc		VISIT 11	06MAR2020	11:09	0	Double Read
					Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
Protruding osteophyte (Central Disc)	5_S	4_5	Central Disc		VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
					Baseline	12JAN2015	12:27	N	Double Read
					VISIT 3A	30MAR2015	11:44	N	Double Read
					VISIT 4	11MAY2015	9:51	N	Double Read
					VISIT 6	09OCT2015	9:25	N	Double Read
Protruding osteophyte (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 7	08APR2016	9:54	N	Double Read
					VISIT 8	24JAN2017	10:51	N	Double Read
					VISIT 11	06MAR2020	11:09	N	Double Read
					VISIT 3A	30MAR2015	11:44	N	Double Read
					VISIT 4	11MAY2015	9:51	N	Double Read
					VISIT 6	09OCT2015	9:25	N	Double Read
					VISIT 7	08APR2016	9:54	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 8	24JAN2017	10:51	N	Double Read
					VISIT 11	06MAR2020	11:09	N	Double Read
Relevant scoliosis	5_S	4_5	General		Baseline	12JAN2015	12:27	N	Double Read
					VISIT 3A	30MAR2015	11:44	N	Double Read
					VISIT 4	11MAY2015	9:51	N	Double Read
					VISIT 6	09OCT2015	9:25	N	Double Read
					VISIT 7	08APR2016	9:54	N	Double Read
					VISIT 8	24JAN2017	10:51	N	Double Read
					VISIT 11	06MAR2020	11:09	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S	4_5	Central Disc		Baseline	12JAN2015	12:27	N	Double Read
					VISIT 3A	30MAR2015	11:44	N	Double Read
					VISIT 4	11MAY2015	9:51	N	Double Read
					VISIT 6	09OCT2015	9:25	N	Double Read
					VISIT 7	08APR2016	9:54	N	Double Read
					VISIT 8	24JAN2017	10:51	N	Double Read
					VISIT 11	06MAR2020	11:09	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	12JAN2015	12:27	N	Double Read
					VISIT 3A	30MAR2015	11:44	N	Double Read
					VISIT 4	11MAY2015	9:51	N	Double Read
					VISIT 6	09OCT2015	9:25	N	Double Read
					VISIT 7	08APR2016	9:54	N	Double Read
					VISIT 8	24JAN2017	10:51	N	Double Read
					VISIT 11	06MAR2020	11:09	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	12JAN2015	12:27	68.08096	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	VISIT 3A	30MAR2015	11:44	67.6016	Double Read
					VISIT 4	11MAY2015	9:51	68.5368	Double Read
					VISIT 6	09OCT2015	9:25	65.07312	Double Read
					VISIT 7	08APR2016	9:54	66.49696	Double Read
					VISIT 8	24JAN2017	10:51	62.8576	Double Read
					VISIT 11	06MAR2020	11:09		Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
T2 (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
T2 (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	12JAN2015	12:27	68.38512	Double Read
					VISIT 3A	30MAR2015	11:44	72.15648	Double Read
					VISIT 4	11MAY2015	9:51	72.3952	Double Read
					VISIT 6	09OCT2015	9:25	73.98656	Double Read
					VISIT 7	08APR2016	9:54	71.12304	Double Read
					VISIT 8	24JAN2017	10:51	69.42224	Double Read
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	VISIT 11	06MAR2020	11:09	67.76384	Double Read
					VISIT 3A	30MAR2015	11:44		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S	4_5	Central Disc		Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 8	24JAN2017	10:51		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		VISIT 11	06MAR2020	11:09		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	12JAN2015	12:27	equal	Double Read
					VISIT 3A	30MAR2015	11:44	equal	Double Read
					VISIT 4	11MAY2015	9:51	equal	Double Read
					VISIT 6	09OCT2015	9:25	lower	Double Read
					VISIT 7	08APR2016	9:54	lower	Double Read
					VISIT 8	24JAN2017	10:51	lower	Double Read
					VISIT 11	06MAR2020	11:09	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44	lower	Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25	lower	Double Read
					VISIT 7	08APR2016	9:54	lower	Double Read
					VISIT 8	24JAN2017	10:51	lower	Double Read
					VISIT 11	06MAR2020	11:09	lower	Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S	4_5	Central Disc		Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S	4_5	Central Disc		VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	12JAN2015	12:27	9.0837710208	Double Read
					VISIT 3A	30MAR2015	11:44	13.210708340	Double Read
					VISIT 4	11MAY2015	9:51	9.4637404450	Double Read
					VISIT 6	09OCT2015	9:25	10.129233905	Double Read
					VISIT 7	08APR2016	9:54	6.3275012739	Double Read
					VISIT 8	24JAN2017	10:51	6.5209580431	Double Read
					VISIT 11	06MAR2020	11:09		Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	12JAN2015	12:27	14.1498216409	Double Read
					VISIT 3A	30MAR2015	11:44	11.5266043825	Double Read
					VISIT 4	11MAY2015	9:51	11.935906234	Double Read
					VISIT 6	09OCT2015	9:25	9.11235603873	Double Read
					VISIT 7	08APR2016	9:54	11.9714965177	Double Read
					VISIT 8	24JAN2017	10:51	9.91153388822	Double Read
					VISIT 11	06MAR2020	11:09	9.16870392392	Double Read
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	12JAN2015	12:27	10764.5	Double Read
					VISIT 3A	30MAR2015	11:44	11003.0	Double Read
					VISIT 4	11MAY2015	9:51	11580.5	Double Read
					VISIT 6	09OCT2015	9:25	10714.5	Double Read
					VISIT 7	08APR2016	9:54	9974.5	Double Read
					VISIT 8	24JAN2017	10:51	9545.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1101 Age=36 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	VISIT 11	06MAR2020	11:09		Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	12JAN2015	12:27	15271.5	Double Read
					VISIT 3A	30MAR2015	11:44	15846.5	Double Read
					VISIT 4	11MAY2015	9:51	16272.5	Double Read
					VISIT 6	09OCT2015	9:25	16713.0	Double Read
					VISIT 7	08APR2016	9:54	15374.0	Double Read
					VISIT 8	24JAN2017	10:51	14664.5	Double Read
					VISIT 11	06MAR2020	11:09		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	12JAN2015	12:27		Double Read
					VISIT 3A	30MAR2015	11:44		Double Read
					VISIT 4	11MAY2015	9:51		Double Read
					VISIT 6	09OCT2015	9:25		Double Read
					VISIT 7	08APR2016	9:54		Double Read
					VISIT 8	24JAN2017	10:51		Double Read
					VISIT 11	06MAR2020	11:09		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	16APR2015	9:40	2	Double Read
					VISIT 3A	27JUL2015	10:08	3	Double Read
					VISIT 4	11SEP2015	9:45	3	Double Read
					VISIT 6	05FEB2016	10:26	3	Double Read
					VISIT 7	29JUL2016	9:53	3	Double Read
					VISIT 8	14JUL2017	10:54	4	Double Read
					VISIT 11	13AUG2020	9:18	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16APR2015	9:40	1	Double Read
					VISIT 3A	27JUL2015	10:08	2	Double Read
					VISIT 4	11SEP2015	9:45	1	Double Read
					VISIT 6	05FEB2016	10:26	2	Double Read
					VISIT 7	29JUL2016	9:53	2	Double Read
					VISIT 8	14JUL2017	10:54	2	Double Read
					VISIT 11	13AUG2020	9:18	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	16APR2015	9:40	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	27JUL2015	10:08	N	Double Read
					VISIT 4	11SEP2015	9:45	N	Double Read
					VISIT 6	05FEB2016	10:26	N	Double Read
					VISIT 7	29JUL2016	9:53	N	Double Read
					VISIT 8	14JUL2017	10:54	N	Double Read
					VISIT 11	13AUG2020	9:18	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16APR2015	9:40	N	Double Read
					VISIT 3A	27JUL2015	10:08	N	Double Read
					VISIT 4	11SEP2015	9:45	N	Double Read
					VISIT 6	05FEB2016	10:26	N	Double Read
					VISIT 7	29JUL2016	9:53	N	Double Read
					VISIT 8	14JUL2017	10:54	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	13AUG2020	9:18	N	Double Read
					Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
					Baseline	16APR2015	9:40	Y	Double Read
					VISIT 3A	27JUL2015	10:08	Y	Double Read
					VISIT 4	11SEP2015	9:45	Y	Double Read
					VISIT 6	05FEB2016	10:26	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	29JUL2016	9:53	Y	Double Read
					VISIT 8	14JUL2017	10:54	N	Double Read
					VISIT 11	13AUG2020	9:18	N	Double Read
					Baseline	16APR2015	9:40	N	Double Read
					VISIT 3A	27JUL2015	10:08	N	Double Read
					VISIT 4	11SEP2015	9:45	N	Double Read
					VISIT 6	05FEB2016	10:26	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	29JUL2016	9:53	N	Double Read
					VISIT 8	14JUL2017	10:54	N	Double Read
					VISIT 11	13AUG2020	9:18	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	16APR2015	9:40	N	Double Read
					VISIT 3A	27JUL2015	10:08	N	Double Read
					VISIT 4	11SEP2015	9:45	N	Double Read
					VISIT 6	05FEB2016	10:26	N	Double Read
					VISIT 7	29JUL2016	9:53	N	Double Read
					VISIT 8	14JUL2017	10:54	N	Double Read
					VISIT 11	13AUG2020	9:18	N	Double Read
Fracture	5_S		General		Baseline	16APR2015	9:40	N	Double Read
					VISIT 3A	27JUL2015	10:08	N	Double Read
					VISIT 4	11SEP2015	9:45	N	Double Read
					VISIT 6	05FEB2016	10:26	N	Double Read
					VISIT 7	29JUL2016	9:53	N	Double Read
					VISIT 8	14JUL2017	10:54	N	Double Read
					VISIT 11	13AUG2020	9:18	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16APR2015	9:40	14.48	Double Read
					VISIT 3A	27JUL2015	10:08	12.595	Double Read
					VISIT 4	11SEP2015	9:45	12.18	Double Read
					VISIT 6	05FEB2016	10:26	12.785	Double Read
					VISIT 7	29JUL2016	9:53	12.76	Double Read
					VISIT 8	14JUL2017	10:54	12.665	Double Read
					VISIT 11	13AUG2020	9:18	12.085	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16APR2015	9:40	14.845	Double Read
					VISIT 3A	27JUL2015	10:08	14.065	Double Read
					VISIT 4	11SEP2015	9:45	15.625	Double Read
					VISIT 6	05FEB2016	10:26	14.28	Double Read
					VISIT 7	29JUL2016	9:53	15.35	Double Read
					VISIT 8	14JUL2017	10:54	15.35	Double Read
					VISIT 11	13AUG2020	9:18	14.62	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16APR2015	9:40	9.75354	Double Read
					VISIT 3A	27JUL2015	10:08	9.01953	Double Read
					VISIT 4	11SEP2015	9:45	9.215475	Double Read
					VISIT 6	05FEB2016	10:26	9.41208	Double Read
					VISIT 7	29JUL2016	9:53	7.35368	Double Read
					VISIT 8	14JUL2017	10:54	8.486595	Double Read
					VISIT 11	13AUG2020	9:18	8.5349	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16APR2015	9:40	13.38585	Double Read
					VISIT 3A	27JUL2015	10:08	12.6408	Double Read
					VISIT 4	11SEP2015	9:45	12.1698	Double Read
					VISIT 6	05FEB2016	10:26	12.6544	Double Read
					VISIT 7	29JUL2016	9:53	11.90835	Double Read
					VISIT 8	14JUL2017	10:54	12.7731	Double Read
					VISIT 11	13AUG2020	9:18	12.48845	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	16APR2015	9:40	N	Double Read
					VISIT 3A	27JUL2015	10:08	N	Double Read
					VISIT 4	11SEP2015	9:45	N	Double Read
					VISIT 6	05FEB2016	10:26	N	Double Read
					VISIT 7	29JUL2016	9:53	N	Double Read
					VISIT 8	14JUL2017	10:54	N	Double Read
					VISIT 11	13AUG2020	9:18	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16APR2015	9:40	N	Double Read
					VISIT 3A	27JUL2015	10:08	N	Double Read
					VISIT 4	11SEP2015	9:45	N	Double Read
					VISIT 6	05FEB2016	10:26	N	Double Read
					VISIT 7	29JUL2016	9:53	N	Double Read
					VISIT 8	14JUL2017	10:54	N	Double Read
					VISIT 11	13AUG2020	9:18	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	16APR2015	9:40	N	Double Read
					VISIT 3A	27JUL2015	10:08	N	Double Read
					VISIT 4	11SEP2015	9:45	N	Double Read
					VISIT 6	05FEB2016	10:26	N	Double Read
					VISIT 7	29JUL2016	9:53	N	Double Read
					VISIT 8	14JUL2017	10:54	N	Double Read
					VISIT 11	13AUG2020	9:18	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16APR2015	9:40	N	Double Read
					VISIT 3A	27JUL2015	10:08	N	Double Read
					VISIT 4	11SEP2015	9:45	N	Double Read
					VISIT 6	05FEB2016	10:26	N	Double Read
					VISIT 7	29JUL2016	9:53	N	Double Read
					VISIT 8	14JUL2017	10:54	N	Double Read
					VISIT 11	13AUG2020	9:18	N	Double Read
Normal lordotic LS	5_S		General		Baseline	16APR2015	9:40	Y	Double Read
					VISIT 3A	27JUL2015	10:08	Y	Double Read
					VISIT 4	11SEP2015	9:45	Y	Double Read
					VISIT 6	05FEB2016	10:26	Y	Double Read
					VISIT 7	29JUL2016	9:53	Y	Double Read
					VISIT 8	14JUL2017	10:54	N	Double Read
					VISIT 11	13AUG2020	9:18	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	16APR2015	9:40	0	Double Read
					VISIT 3A	27JUL2015	10:08	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	11SEP2015	9:45	0	Double Read
					VISIT 6	05FEB2016	10:26	0	Double Read
					VISIT 7	29JUL2016	9:53	1	Double Read
					VISIT 8	14JUL2017	10:54	0	Double Read
					VISIT 11	13AUG2020	9:18	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16APR2015	9:40	0	Double Read
					VISIT 3A	27JUL2015	10:08	0	Double Read
					VISIT 4	11SEP2015	9:45	0	Double Read
					VISIT 6	05FEB2016	10:26	0	Double Read
					VISIT 7	29JUL2016	9:53	0	Double Read
					VISIT 8	14JUL2017	10:54	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 11	13AUG2020	9:18	0	Double Read
					Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
					Baseline	16APR2015	9:40	N	Double Read
					VISIT 3A	27JUL2015	10:08	N	Double Read
					VISIT 4	11SEP2015	9:45	N	Double Read
					VISIT 6	05FEB2016	10:26	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	29JUL2016	9:53	N	Double Read
					VISIT 8	14JUL2017	10:54	N	Double Read
					VISIT 11	13AUG2020	9:18	Y	Double Read
					Baseline	16APR2015	9:40	N	Double Read
					VISIT 3A	27JUL2015	10:08	N	Double Read
					VISIT 4	11SEP2015	9:45	N	Double Read
					VISIT 6	05FEB2016	10:26	N	Double Read
					VISIT 7	29JUL2016	9:53	N	Double Read
					VISIT 8	14JUL2017	10:54	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	14JUL2017	10:54	N	Double Read
					VISIT 11	13AUG2020	9:18	N	Double Read
Relevant scoliosis	5_S		General		Baseline	16APR2015	9:40	N	Double Read
					VISIT 3A	27JUL2015	10:08	N	Double Read
					VISIT 4	11SEP2015	9:45	N	Double Read
					VISIT 6	05FEB2016	10:26	N	Double Read
					VISIT 7	29JUL2016	9:53	N	Double Read
					VISIT 8	14JUL2017	10:54	N	Double Read
					VISIT 11	13AUG2020	9:18	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	16APR2015	9:40	N	Double Read
					VISIT 3A	27JUL2015	10:08	N	Double Read
					VISIT 4	11SEP2015	9:45	N	Double Read
					VISIT 6	05FEB2016	10:26	N	Double Read
					VISIT 7	29JUL2016	9:53	N	Double Read
					VISIT 8	14JUL2017	10:54	N	Double Read
					VISIT 11	13AUG2020	9:18	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	16APR2015	9:40	N	Double Read
					VISIT 3A	27JUL2015	10:08	N	Double Read
					VISIT 4	11SEP2015	9:45	N	Double Read
					VISIT 6	05FEB2016	10:26	N	Double Read
					VISIT 7	29JUL2016	9:53	N	Double Read
					VISIT 8	14JUL2017	10:54	N	Double Read
					VISIT 11	13AUG2020	9:18	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16APR2015	9:40	74.15648	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	27JUL2015	10:08	68.788	Double Read
					VISIT 4	11SEP2015	9:45	62.87392	Double Read
					VISIT 6	05FEB2016	10:26	68.4072	Double Read
					VISIT 7	29JUL2016	9:53	68.77376	Double Read
					VISIT 8	14JUL2017	10:54	65.33232	Double Read
					VISIT 11	13AUG2020	9:18	58.38864	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16APR2015	9:40	90.17136	Double Read
					VISIT 3A	27JUL2015	10:08	98.19648	Double Read
					VISIT 4	11SEP2015	9:45	96.33424	Double Read
					VISIT 6	05FEB2016	10:26	94.268	Double Read
					VISIT 7	29JUL2016	9:53	99.13824	Double Read
					VISIT 8	14JUL2017	10:54	101.71024	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	13AUG2020	9:18	99.2992	Double Read
					VISIT 3A	27JUL2015	10:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 8	14JUL2017	10:54		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	13AUG2020	9:18		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	16APR2015	9:40	lower	Double Read
					VISIT 3A	27JUL2015	10:08	lower	Double Read
					VISIT 4	11SEP2015	9:45	lower	Double Read
					VISIT 6	05FEB2016	10:26	lower	Double Read
					VISIT 7	29JUL2016	9:53	lower	Double Read
					VISIT 8	14JUL2017	10:54	lower	Double Read
					VISIT 11	13AUG2020	9:18	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16APR2015	9:40	5.0615050110	Double Read
					VISIT 3A	27JUL2015	10:08	6.6813861049	Double Read
					VISIT 4	11SEP2015	9:45	9.9464515033	Double Read
					VISIT 6	05FEB2016	10:26	12.909801257	Double Read
					VISIT 7	29JUL2016	9:53	12.826220485	Double Read
					VISIT 8	14JUL2017	10:54	5.7754374044	Double Read
					VISIT 11	13AUG2020	9:18	5.3224596568	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16APR2015	9:40	6.0019228809	Double Read
					VISIT 3A	27JUL2015	10:08	2.3026261253	Double Read
					VISIT 4	11SEP2015	9:45	5.5449023271	Double Read
					VISIT 6	05FEB2016	10:26	4.4908510276	Double Read
					VISIT 7	29JUL2016	9:53	5.0797961610	Double Read
					VISIT 8	14JUL2017	10:54	5.7754374044	Double Read
					VISIT 11	13AUG2020	9:18	3.9210667572	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	16APR2015	9:40	16356.5	Double Read
					VISIT 3A	27JUL2015	10:08	13431.5	Double Read
					VISIT 4	11SEP2015	9:45	14428.0	Double Read
					VISIT 6	05FEB2016	10:26	15005.0	Double Read
					VISIT 7	29JUL2016	9:53	14054.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	14JUL2017	10:54	14556.5	Double Read
					VISIT 11	13AUG2020	9:18	15466.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read
					VISIT 11	13AUG2020	9:18		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	16APR2015	9:40	20212.0	Double Read
					VISIT 3A	27JUL2015	10:08	18458.0	Double Read
					VISIT 4	11SEP2015	9:45	19925.0	Double Read
					VISIT 6	05FEB2016	10:26	19872.0	Double Read
					VISIT 7	29JUL2016	9:53	19702.0	Double Read
					VISIT 8	14JUL2017	10:54	20168.0	Double Read
					VISIT 11	13AUG2020	9:18	19188.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	16APR2015	9:40		Double Read
					VISIT 3A	27JUL2015	10:08		Double Read
					VISIT 4	11SEP2015	9:45		Double Read
					VISIT 6	05FEB2016	10:26		Double Read
					VISIT 7	29JUL2016	9:53		Double Read
					VISIT 8	14JUL2017	10:54		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1102 Age=23 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	13AUG2020	9:18		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	30JUL2015	10:08	3	Double Read
					VISIT 4	18SEP2015	10:01	3	Double Read
					VISIT 6	12FEB2016	9:47	3	Double Read
					VISIT 7	05AUG2016	9:52	3	Double Read
					VISIT 8	04AUG2017	10:37	3	Double Read
					VISIT 11	20AUG2020	8:20	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	30JUL2015	10:08	2	Double Read
					VISIT 4	18SEP2015	10:01	3	Double Read
					VISIT 6	12FEB2016	9:47	2	Double Read
					VISIT 7	05AUG2016	9:52	2	Double Read
					VISIT 8	04AUG2017	10:37	2	Double Read
					VISIT 11	20AUG2020	8:20	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	30JUL2015	10:08	N	Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47	N	Double Read
					VISIT 7	05AUG2016	9:52	N	Double Read
					VISIT 8	04AUG2017	10:37	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 11	20AUG2020	8:20	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	30JUL2015	10:08	N	Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47	N	Double Read
					VISIT 7	05AUG2016	9:52	N	Double Read
					VISIT 8	04AUG2017	10:37	N	Double Read
					VISIT 11	20AUG2020	8:20	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	30JUL2015	10:08	Y	Double Read
					VISIT 4	18SEP2015	10:01	Y	Double Read
					VISIT 6	12FEB2016	9:47	N	Double Read
					VISIT 7	05AUG2016	9:52	N	Double Read
					VISIT 8	04AUG2017	10:37	Y	Double Read
					VISIT 11	20AUG2020	8:20	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	30JUL2015	10:08	N	Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47	N	Double Read
					VISIT 7	05AUG2016	9:52	N	Double Read
					VISIT 8	04AUG2017	10:37	N	Double Read
					VISIT 11	20AUG2020	8:20	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	30JUL2015	10:08	N	Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47	N	Double Read
					VISIT 7	05AUG2016	9:52	N	Double Read
					VISIT 8	04AUG2017	10:37	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 11	20AUG2020	8:20	N	Double Read
Fracture	5_S		General		Baseline	30JUL2015	10:08	N	Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47	N	Double Read
					VISIT 7	05AUG2016	9:52	N	Double Read
					VISIT 8	04AUG2017	10:37	N	Double Read
					VISIT 11	20AUG2020	8:20	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	30JUL2015	10:08	13.54	Double Read
					VISIT 4	18SEP2015	10:01	14.545	Double Read
					VISIT 6	12FEB2016	9:47	14.255	Double Read
					VISIT 7	05AUG2016	9:52	12.98	Double Read
					VISIT 8	04AUG2017	10:37	15.29	Double Read
					VISIT 11	20AUG2020	8:20	10.94	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	30JUL2015	10:08	13.595	Double Read
					VISIT 4	18SEP2015	10:01	15.03	Double Read
					VISIT 6	12FEB2016	9:47	14.805	Double Read
					VISIT 7	05AUG2016	9:52	13.625	Double Read
					VISIT 8	04AUG2017	10:37	15.605	Double Read
					VISIT 11	20AUG2020	8:20	14.85	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	30JUL2015	10:08	8.16158	Double Read
					VISIT 4	18SEP2015	10:01	8.336905	Double Read
					VISIT 6	12FEB2016	9:47	8.975025	Double Read
					VISIT 7	05AUG2016	9:52	8.374045	Double Read
					VISIT 8	04AUG2017	10:37	8.885375	Double Read
					VISIT 11	20AUG2020	8:20	5.61921	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	30JUL2015	10:08	10.5939	Double Read
					VISIT 4	18SEP2015	10:01	9.831035	Double Read
					VISIT 6	12FEB2016	9:47	11.2307	Double Read
					VISIT 7	05AUG2016	9:52	11.13145	Double Read
					VISIT 8	04AUG2017	10:37	11.5667	Double Read
					VISIT 11	20AUG2020	8:20	11.82235	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	30JUL2015	10:08	N	Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47	N	Double Read
					VISIT 7	05AUG2016	9:52	N	Double Read
					VISIT 8	04AUG2017	10:37	N	Double Read
					VISIT 11	20AUG2020	8:20	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	30JUL2015	10:08	N	Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47	N	Double Read
					VISIT 7	05AUG2016	9:52	N	Double Read
					VISIT 8	04AUG2017	10:37	N	Double Read
					VISIT 11	20AUG2020	8:20	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	30JUL2015	10:08	N	Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47	N	Double Read
					VISIT 7	05AUG2016	9:52	N	Double Read
					VISIT 8	04AUG2017	10:37	N	Double Read
					VISIT 11	20AUG2020	8:20	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	30JUL2015	10:08	N	Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47	N	Double Read
					VISIT 7	05AUG2016	9:52	N	Double Read
					VISIT 8	04AUG2017	10:37	N	Double Read
					VISIT 11	20AUG2020	8:20	N	Double Read
Normal lordotic LS	5_S		General		Baseline	30JUL2015	10:08	Y	Double Read
					VISIT 4	18SEP2015	10:01	Y	Double Read
					VISIT 6	12FEB2016	9:47	Y	Double Read
					VISIT 7	05AUG2016	9:52	Y	Double Read
					VISIT 8	04AUG2017	10:37	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	5_S		General		VISIT 11	20AUG2020	8:20	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01	0	Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	30JUL2015	10:08	0	Double Read
					VISIT 4	18SEP2015	10:01	0	Double Read
					VISIT 6	12FEB2016	9:47	0	Double Read
					VISIT 7	05AUG2016	9:52	1	Double Read
					VISIT 8	04AUG2017	10:37	1	Double Read
					VISIT 11	20AUG2020	8:20	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	30JUL2015	10:08	0	Double Read
					VISIT 4	18SEP2015	10:01	0	Double Read
					VISIT 6	12FEB2016	9:47	0	Double Read
					VISIT 7	05AUG2016	9:52	0	Double Read
					VISIT 8	04AUG2017	10:37	0	Double Read
					VISIT 11	20AUG2020	8:20	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	30JUL2015	10:08	N	Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47	N	Double Read
					VISIT 7	05AUG2016	9:52	N	Double Read
					VISIT 8	04AUG2017	10:37	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 11	20AUG2020	8:20	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	30JUL2015	10:08	N	Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47	N	Double Read
					VISIT 7	05AUG2016	9:52	N	Double Read
					VISIT 8	04AUG2017	10:37	N	Double Read
					VISIT 11	20AUG2020	8:20	N	Double Read
Relevant scoliosis	5_S		General		Baseline	30JUL2015	10:08	N	Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47	N	Double Read
					VISIT 7	05AUG2016	9:52	N	Double Read
					VISIT 8	04AUG2017	10:37	N	Double Read
					VISIT 11	20AUG2020	8:20	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	30JUL2015	10:08	N	Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47	N	Double Read
					VISIT 7	05AUG2016	9:52	N	Double Read
					VISIT 8	04AUG2017	10:37	N	Double Read
					VISIT 11	20AUG2020	8:20	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	30JUL2015	10:08	N	Double Read
					VISIT 4	18SEP2015	10:01	N	Double Read
					VISIT 6	12FEB2016	9:47	N	Double Read
					VISIT 7	05AUG2016	9:52	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	04AUG2017	10:37	N	Double Read
					VISIT 11	20AUG2020	8:20	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	30JUL2015	10:08	64.71456	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 4	18SEP2015	10:01	64.30736	Double Read
					VISIT 6	12FEB2016	9:47	64.1048	Double Read
					VISIT 7	05AUG2016	9:52	67.51664	Double Read
					VISIT 8	04AUG2017	10:37	65.7824	Double Read
					VISIT 11	20AUG2020	8:20	78.8544	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	30JUL2015	10:08	72.49296	Double Read
					VISIT 4	18SEP2015	10:01	75.1632	Double Read
					VISIT 6	12FEB2016	9:47	72.87168	Double Read
					VISIT 7	05AUG2016	9:52	74.65872	Double Read
					VISIT 8	04AUG2017	10:37	75.04224	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20	71.99904	Double Read
					VISIT 11	20AUG2020	8:20		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
					VISIT 11	20AUG2020	8:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	30JUL2015	10:08	lower	Double Read
					VISIT 4	18SEP2015	10:01	equal	Double Read
					VISIT 6	12FEB2016	9:47	lower	Double Read
					VISIT 7	05AUG2016	9:52	lower	Double Read
					VISIT 8	04AUG2017	10:37	lower	Double Read
					VISIT 11	20AUG2020	8:20	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	30JUL2015	10:08	8.4864888737	Double Read
					VISIT 4	18SEP2015	10:01	4.5966434516	Double Read
					VISIT 6	12FEB2016	9:47	9.7012264311	Double Read
					VISIT 7	05AUG2016	9:52	2.0387429930	Double Read
					VISIT 8	04AUG2017	10:37	9.3614948191	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 11	20AUG2020	8:20	8.01766604383	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	30JUL2015	10:08	11.0035264141	Double Read
					VISIT 4	18SEP2015	10:01	8.3079870902	Double Read
					VISIT 6	12FEB2016	9:47	9.45071513504	Double Read
					VISIT 7	05AUG2016	9:52	5.54895192798	Double Read
					VISIT 8	04AUG2017	10:37	9.09348055036	Double Read
					VISIT 11	20AUG2020	8:20	5.87735688806	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	30JUL2015	10:08	10338.5	Double Read
					VISIT 4	18SEP2015	10:01	11238.5	Double Read
					VISIT 6	12FEB2016	9:47	11473.5	Double Read
					VISIT 7	05AUG2016	9:52	10046.5	Double Read
					VISIT 8	04AUG2017	10:37	12443.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1103 Age=41 Sex=Female Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 11	20AUG2020	8:20	10312.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	30JUL2015	10:08	14312.5	Double Read
					VISIT 4	18SEP2015	10:01	16635.0	Double Read
					VISIT 6	12FEB2016	9:47	16308.0	Double Read
					VISIT 7	05AUG2016	9:52	14942.5	Double Read
					VISIT 8	04AUG2017	10:37	15500.5	Double Read
					VISIT 11	20AUG2020	8:20	15477.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	30JUL2015	10:08		Double Read
					VISIT 4	18SEP2015	10:01		Double Read
					VISIT 6	12FEB2016	9:47		Double Read
					VISIT 7	05AUG2016	9:52		Double Read
					VISIT 8	04AUG2017	10:37		Double Read
					VISIT 11	20AUG2020	8:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	01MAR2016	11:19	3	Double Read
					VISIT 3A	06JUN2016	11:53	3	Double Read
					VISIT 4	22JUL2016	10:16	3	Double Read
					VISIT 6	25NOV2016	10:41	3	Double Read
					VISIT 7	30MAY2017	10:55	3	Double Read
					VISIT 8	12JUN2018	12:11	3	Double Read
					VISIT 11	28MAY2021	9:24	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	01MAR2016	11:19	2	Double Read
					VISIT 3A	06JUN2016	11:53	2	Double Read
					VISIT 4	22JUL2016	10:16	2	Double Read
					VISIT 6	25NOV2016	10:41	2	Double Read
					VISIT 7	30MAY2017	10:55	2	Double Read
					VISIT 8	12JUN2018	12:11	2	Double Read
					VISIT 11	28MAY2021	9:24	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	01MAR2016	11:19	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	06JUN2016	11:53	N	Double Read
					VISIT 4	22JUL2016	10:16	N	Double Read
					VISIT 6	25NOV2016	10:41	N	Double Read
					VISIT 7	30MAY2017	10:55	N	Double Read
					VISIT 8	12JUN2018	12:11	N	Double Read
					VISIT 11	28MAY2021	9:24	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	01MAR2016	11:19	N	Double Read
					VISIT 3A	06JUN2016	11:53	N	Double Read
					VISIT 4	22JUL2016	10:16	N	Double Read
					VISIT 6	25NOV2016	10:41	N	Double Read
					VISIT 7	30MAY2017	10:55	N	Double Read
					VISIT 8	12JUN2018	12:11	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	28MAY2021	9:24	N	Double Read
					Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
					Baseline	01MAR2016	11:19	Y	Double Read
					VISIT 3A	06JUN2016	11:53	Y	Double Read
					VISIT 4	22JUL2016	10:16	Y	Double Read
					VISIT 6	25NOV2016	10:41	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	30MAY2017	10:55	Y	Double Read
					VISIT 8	12JUN2018	12:11	Y	Double Read
					VISIT 11	28MAY2021	9:24	N	Double Read
					Baseline	01MAR2016	11:19	N	Double Read
					VISIT 3A	06JUN2016	11:53	N	Double Read
					VISIT 4	22JUL2016	10:16	N	Double Read
					VISIT 6	25NOV2016	10:41	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	30MAY2017	10:55	Y	Double Read
					VISIT 8	12JUN2018	12:11	N	Double Read
					VISIT 11	28MAY2021	9:24	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	01MAR2016	11:19	N	Double Read
					VISIT 3A	06JUN2016	11:53	N	Double Read
					VISIT 4	22JUL2016	10:16	N	Double Read
					VISIT 6	25NOV2016	10:41	N	Double Read
					VISIT 7	30MAY2017	10:55	N	Double Read
					VISIT 8	12JUN2018	12:11	N	Double Read
					VISIT 11	28MAY2021	9:24	N	Double Read
Fracture	5_S		General		Baseline	01MAR2016	11:19	N	Double Read
					VISIT 3A	06JUN2016	11:53	N	Double Read
					VISIT 4	22JUL2016	10:16	N	Double Read
					VISIT 6	25NOV2016	10:41	N	Double Read
					VISIT 7	30MAY2017	10:55	N	Double Read
					VISIT 8	12JUN2018	12:11	N	Double Read
					VISIT 11	28MAY2021	9:24	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	01MAR2016	11:19	16.505	Double Read
					VISIT 3A	06JUN2016	11:53	17.145	Double Read
					VISIT 4	22JUL2016	10:16	15.965	Double Read
					VISIT 6	25NOV2016	10:41	14.9	Double Read
					VISIT 7	30MAY2017	10:55	15.23	Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24	15.305	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	01MAR2016	11:19	16.46	Double Read
					VISIT 3A	06JUN2016	11:53	16.935	Double Read
					VISIT 4	22JUL2016	10:16	16.755	Double Read
					VISIT 6	25NOV2016	10:41	15.405	Double Read
					VISIT 7	30MAY2017	10:55	16.51	Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24	16.47	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	01MAR2016	11:19	8.42801	Double Read
					VISIT 3A	06JUN2016	11:53	8.86481	Double Read
					VISIT 4	22JUL2016	10:16	9.495425	Double Read
					VISIT 6	25NOV2016	10:41	9.453605	Double Read
					VISIT 7	30MAY2017	10:55	9.587325	Double Read
					VISIT 8	12JUN2018	12:11	9.895785	Double Read
					VISIT 11	28MAY2021	9:24	5.613625	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	01MAR2016	11:19	10.8117	Double Read
					VISIT 3A	06JUN2016	11:53	10.8239	Double Read
					VISIT 4	22JUL2016	10:16	10.94225	Double Read
					VISIT 6	25NOV2016	10:41	10.7566	Double Read
					VISIT 7	30MAY2017	10:55	11.1515	Double Read
					VISIT 8	12JUN2018	12:11	11.7019	Double Read
					VISIT 11	28MAY2021	9:24	10.9477	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	01MAR2016	11:19	N	Double Read
					VISIT 3A	06JUN2016	11:53	N	Double Read
					VISIT 4	22JUL2016	10:16	N	Double Read
					VISIT 6	25NOV2016	10:41	N	Double Read
					VISIT 7	30MAY2017	10:55	N	Double Read
					VISIT 8	12JUN2018	12:11	N	Double Read
					VISIT 11	28MAY2021	9:24	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	01MAR2016	11:19	N	Double Read
					VISIT 3A	06JUN2016	11:53	N	Double Read
					VISIT 4	22JUL2016	10:16	N	Double Read
					VISIT 6	25NOV2016	10:41	N	Double Read
					VISIT 7	30MAY2017	10:55	Y	Double Read
					VISIT 8	12JUN2018	12:11	N	Double Read
					VISIT 11	28MAY2021	9:24	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	01MAR2016	11:19	N	Double Read
					VISIT 3A	06JUN2016	11:53	N	Double Read
					VISIT 4	22JUL2016	10:16	N	Double Read
					VISIT 6	25NOV2016	10:41	N	Double Read
					VISIT 7	30MAY2017	10:55	N	Double Read
					VISIT 8	12JUN2018	12:11	N	Double Read
					VISIT 11	28MAY2021	9:24	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	01MAR2016	11:19	N	Double Read
					VISIT 3A	06JUN2016	11:53	N	Double Read
					VISIT 4	22JUL2016	10:16	N	Double Read
					VISIT 6	25NOV2016	10:41	N	Double Read
					VISIT 7	30MAY2017	10:55	N	Double Read
					VISIT 8	12JUN2018	12:11	N	Double Read
					VISIT 11	28MAY2021	9:24	N	Double Read
Normal lordotic LS	5_S		General		Baseline	01MAR2016	11:19	Y	Double Read
					VISIT 3A	06JUN2016	11:53	Y	Double Read
					VISIT 4	22JUL2016	10:16	Y	Double Read
					VISIT 6	25NOV2016	10:41	Y	Double Read
					VISIT 7	30MAY2017	10:55	Y	Double Read
					VISIT 8	12JUN2018	12:11	Y	Double Read
					VISIT 11	28MAY2021	9:24	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	01MAR2016	11:19	0	Double Read
					VISIT 3A	06JUN2016	11:53	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	22JUL2016	10:16	1	Double Read
					VISIT 6	25NOV2016	10:41	1	Double Read
					VISIT 7	30MAY2017	10:55	1	Double Read
					VISIT 8	12JUN2018	12:11	2	Double Read
					VISIT 11	28MAY2021	9:24	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	01MAR2016	11:19	0	Double Read
					VISIT 3A	06JUN2016	11:53	0	Double Read
					VISIT 4	22JUL2016	10:16	0	Double Read
					VISIT 6	25NOV2016	10:41	0	Double Read
					VISIT 7	30MAY2017	10:55	0	Double Read
					VISIT 8	12JUN2018	12:11	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 11	28MAY2021	9:24	0	Double Read
					Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
					Baseline	01MAR2016	11:19	N	Double Read
					VISIT 3A	06JUN2016	11:53	N	Double Read
					VISIT 4	22JUL2016	10:16	N	Double Read
					VISIT 6	25NOV2016	10:41	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	30MAY2017	10:55	N	Double Read
					VISIT 8	12JUN2018	12:11	N	Double Read
					VISIT 11	28MAY2021	9:24	N	Double Read
					Baseline	01MAR2016	11:19	N	Double Read
					VISIT 3A	06JUN2016	11:53	N	Double Read
					VISIT 4	22JUL2016	10:16	N	Double Read
					VISIT 6	25NOV2016	10:41	N	Double Read
					VISIT 7	30MAY2017	10:55	N	Double Read
					VISIT 8	12JUN2018	12:11	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	12JUN2018	12:11	N	Double Read
					VISIT 11	28MAY2021	9:24	N	Double Read
Relevant scoliosis	5_S		General		Baseline	01MAR2016	11:19	N	Double Read
					VISIT 3A	06JUN2016	11:53	N	Double Read
					VISIT 4	22JUL2016	10:16	N	Double Read
					VISIT 6	25NOV2016	10:41	N	Double Read
					VISIT 7	30MAY2017	10:55	N	Double Read
					VISIT 8	12JUN2018	12:11	N	Double Read
					VISIT 11	28MAY2021	9:24	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	01MAR2016	11:19	N	Double Read
					VISIT 3A	06JUN2016	11:53	N	Double Read
					VISIT 4	22JUL2016	10:16	N	Double Read
					VISIT 6	25NOV2016	10:41	N	Double Read
					VISIT 7	30MAY2017	10:55	N	Double Read
					VISIT 8	12JUN2018	12:11	N	Double Read
					VISIT 11	28MAY2021	9:24	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	01MAR2016	11:19	N	Double Read
					VISIT 3A	06JUN2016	11:53	N	Double Read
					VISIT 4	22JUL2016	10:16	N	Double Read
					VISIT 6	25NOV2016	10:41	N	Double Read
					VISIT 7	30MAY2017	10:55	N	Double Read
					VISIT 8	12JUN2018	12:11	N	Double Read
					VISIT 11	28MAY2021	9:24	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	01MAR2016	11:19	63.5392	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	06JUN2016	11:53	82.00416	Double Read
					VISIT 4	22JUL2016	10:16	81.68656	Double Read
					VISIT 6	25NOV2016	10:41	80.9248	Double Read
					VISIT 7	30MAY2017	10:55	81.55344	Double Read
					VISIT 8	12JUN2018	12:11	71.99552	Double Read
					VISIT 11	28MAY2021	9:24	74.5584	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	VISIT 11	28MAY2021	9:24		Double Read
					Baseline	01MAR2016	11:19	87.47744	Double Read
					VISIT 3A	06JUN2016	11:53	86.97712	Double Read
					VISIT 4	22JUL2016	10:16	84.64144	Double Read
					VISIT 6	25NOV2016	10:41	83.51136	Double Read
					VISIT 7	30MAY2017	10:55	81.39344	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	12JUN2018	12:11	75.67552	Double Read
					VISIT 11	28MAY2021	9:24	72.168	Double Read
					Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 8	12JUN2018	12:11		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	28MAY2021	9:24		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	01MAR2016	11:19	lower	Double Read
					VISIT 3A	06JUN2016	11:53	lower	Double Read
					VISIT 4	22JUL2016	10:16	lower	Double Read
					VISIT 6	25NOV2016	10:41	lower	Double Read
					VISIT 7	30MAY2017	10:55	lower	Double Read
					VISIT 8	12JUN2018	12:11	lower	Double Read
					VISIT 11	28MAY2021	9:24	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	01MAR2016	11:19	11.5098895872	Double Read
					VISIT 3A	06JUN2016	11:53	8.8783149312	Double Read
					VISIT 4	22JUL2016	10:16	9.76162391709	Double Read
					VISIT 6	25NOV2016	10:41	4.50166808221	Double Read
					VISIT 7	30MAY2017	10:55	12.1397452013	Double Read
					VISIT 8	12JUN2018	12:11	15.6761678274	Double Read
					VISIT 11	28MAY2021	9:24	12.2255953797	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	01MAR2016	11:19	5.0012434177	Double Read
					VISIT 3A	06JUN2016	11:53	11.2111431969	Double Read
					VISIT 4	22JUL2016	10:16	11.5023407508	Double Read
					VISIT 6	25NOV2016	10:41	15.1601155087	Double Read
					VISIT 7	30MAY2017	10:55	15.2596093086	Double Read
					VISIT 8	12JUN2018	12:11	10.6226804824	Double Read
					VISIT 11	28MAY2021	9:24	13.6911839646	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	01MAR2016	11:19	14913.5	Double Read
					VISIT 3A	06JUN2016	11:53	15859.5	Double Read
					VISIT 4	22JUL2016	10:16	15358.5	Double Read
					VISIT 6	25NOV2016	10:41	15225.0	Double Read
					VISIT 7	30MAY2017	10:55	14375.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24	14363.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	01MAR2016	11:19	20537.0	Double Read
					VISIT 3A	06JUN2016	11:53	21458.5	Double Read
					VISIT 4	22JUL2016	10:16	21057.5	Double Read
					VISIT 6	25NOV2016	10:41	20402.5	Double Read
					VISIT 7	30MAY2017	10:55	21094.5	Double Read
					VISIT 8	12JUN2018	12:11		Double Read
					VISIT 11	28MAY2021	9:24	21037.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	01MAR2016	11:19		Double Read
					VISIT 3A	06JUN2016	11:53		Double Read
					VISIT 4	22JUL2016	10:16		Double Read
					VISIT 6	25NOV2016	10:41		Double Read
					VISIT 7	30MAY2017	10:55		Double Read
					VISIT 8	12JUN2018	12:11		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=11/1104 Age=43 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	28MAY2021	9:24		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	04SEP2015	8:34	3	Double Read
					VISIT 3A	30NOV2015	13:57	3	Double Read
					VISIT 4	08JAN2016	9:35	3	Double Read
					VISIT 6	18MAY2016	8:50	3	Double Read
					VISIT 7	22NOV2016	8:13	3	Double Read
					VISIT 8	21NOV2017	8:08	3	Double Read
					VISIT 11	01DEC2020	9:58	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04SEP2015	8:34	3	Double Read
					VISIT 3A	30NOV2015	13:57	3	Double Read
					VISIT 4	08JAN2016	9:35	3	Double Read
					VISIT 6	18MAY2016	8:50	3	Double Read
					VISIT 7	22NOV2016	8:13	3	Double Read
					VISIT 8	21NOV2017	8:08	3	Double Read
					VISIT 11	01DEC2020	9:58	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	04SEP2015	8:34	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	30NOV2015	13:57	N	Double Read
					VISIT 4	08JAN2016	9:35	N	Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
					VISIT 7	22NOV2016	8:13	N	Double Read
					VISIT 8	21NOV2017	8:08	N	Double Read
					VISIT 11	01DEC2020	9:58	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04SEP2015	8:34	N	Double Read
					VISIT 3A	30NOV2015	13:57	N	Double Read
					VISIT 4	08JAN2016	9:35	N	Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
					VISIT 7	22NOV2016	8:13	N	Double Read
					VISIT 8	21NOV2017	8:08	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	01DEC2020	9:58	N	Double Read
					Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
					VISIT 7	22NOV2016	8:13		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
					Baseline	04SEP2015	8:34	Y	Double Read
					VISIT 3A	30NOV2015	13:57	Y	Double Read
					VISIT 4	08JAN2016	9:35	Y	Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	22NOV2016	8:13	Y	Double Read
					VISIT 8	21NOV2017	8:08	Y	Double Read
					VISIT 11	01DEC2020	9:58	Y	Double Read
					Baseline	04SEP2015	8:34	N	Double Read
					VISIT 3A	30NOV2015	13:57	N	Double Read
					VISIT 4	08JAN2016	9:35	N	Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	22NOV2016	8:13	N	Double Read
					VISIT 8	21NOV2017	8:08	N	Double Read
					VISIT 11	01DEC2020	9:58	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	04SEP2015	8:34	N	Double Read
					VISIT 3A	30NOV2015	13:57	N	Double Read
					VISIT 4	08JAN2016	9:35	N	Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
					VISIT 7	22NOV2016	8:13	N	Double Read
					VISIT 8	21NOV2017	8:08	N	Double Read
					VISIT 11	01DEC2020	9:58	N	Double Read
Fracture	5_S		General		Baseline	04SEP2015	8:34	N	Double Read
					VISIT 3A	30NOV2015	13:57	N	Double Read
					VISIT 4	08JAN2016	9:35	N	Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
					VISIT 7	22NOV2016	8:13	N	Double Read
					VISIT 8	21NOV2017	8:08	N	Double Read
					VISIT 11	01DEC2020	9:58	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	04SEP2015	8:34	12.69	Double Read
					VISIT 3A	30NOV2015	13:57	13.08	Double Read
					VISIT 4	08JAN2016	9:35	12.85	Double Read
					VISIT 6	18MAY2016	8:50	12.805	Double Read
					VISIT 7	22NOV2016	8:13	13.07	Double Read
					VISIT 8	21NOV2017	8:08	19.685	Double Read
					VISIT 11	01DEC2020	9:58	10.265	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	04SEP2015	8:34	12.515	Double Read
					VISIT 3A	30NOV2015	13:57	12.625	Double Read
					VISIT 4	08JAN2016	9:35	11.92	Double Read
					VISIT 6	18MAY2016	8:50	12.305	Double Read
					VISIT 7	22NOV2016	8:13	12.845	Double Read
					VISIT 8	21NOV2017	8:08	13.035	Double Read
					VISIT 11	01DEC2020	9:58	11.265	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	04SEP2015	8:34	8.011205	Double Read
					VISIT 3A	30NOV2015	13:57	7.788915	Double Read
					VISIT 4	08JAN2016	9:35	8.47978	Double Read
					VISIT 6	18MAY2016	8:50	8.42128	Double Read
					VISIT 7	22NOV2016	8:13	7.86495	Double Read
					VISIT 8	21NOV2017	8:08	7.836525	Double Read
					VISIT 11	01DEC2020	9:58	7.183345	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	04SEP2015	8:34	10.2419	Double Read
					VISIT 3A	30NOV2015	13:57	9.788585	Double Read
					VISIT 4	08JAN2016	9:35	10.77435	Double Read
					VISIT 6	18MAY2016	8:50	9.737455	Double Read
					VISIT 7	22NOV2016	8:13	10.09907	Double Read
					VISIT 8	21NOV2017	8:08	10.66025	Double Read
					VISIT 11	01DEC2020	9:58	9.30281	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	04SEP2015	8:34	N	Double Read
					VISIT 3A	30NOV2015	13:57	N	Double Read
					VISIT 4	08JAN2016	9:35	N	Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
					VISIT 7	22NOV2016	8:13	N	Double Read
					VISIT 8	21NOV2017	8:08	N	Double Read
					VISIT 11	01DEC2020	9:58	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04SEP2015	8:34	N	Double Read
					VISIT 3A	30NOV2015	13:57	N	Double Read
					VISIT 4	08JAN2016	9:35	N	Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
					VISIT 7	22NOV2016	8:13	N	Double Read
					VISIT 8	21NOV2017	8:08	N	Double Read
					VISIT 11	01DEC2020	9:58	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	04SEP2015	8:34	N	Double Read
					VISIT 3A	30NOV2015	13:57	N	Double Read
					VISIT 4	08JAN2016	9:35	N	Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
					VISIT 7	22NOV2016	8:13	N	Double Read
					VISIT 8	21NOV2017	8:08	N	Double Read
					VISIT 11	01DEC2020	9:58	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04SEP2015	8:34	N	Double Read
					VISIT 3A	30NOV2015	13:57	N	Double Read
					VISIT 4	08JAN2016	9:35	N	Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
					VISIT 7	22NOV2016	8:13	N	Double Read
					VISIT 8	21NOV2017	8:08	N	Double Read
					VISIT 11	01DEC2020	9:58	N	Double Read
Normal lordotic LS	5_S		General		Baseline	04SEP2015	8:34	Y	Double Read
					VISIT 3A	30NOV2015	13:57	Y	Double Read
					VISIT 4	08JAN2016	9:35	Y	Double Read
					VISIT 6	18MAY2016	8:50	Y	Double Read
					VISIT 7	22NOV2016	8:13	Y	Double Read
					VISIT 8	21NOV2017	8:08	Y	Double Read
					VISIT 11	01DEC2020	9:58	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	04SEP2015	8:34	0	Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	04SEP2015	8:34	0	Double Read
					VISIT 3A	30NOV2015	13:57	1	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	08JAN2016	9:35	1	Double Read
					VISIT 6	18MAY2016	8:50	1	Double Read
					VISIT 7	22NOV2016	8:13	1	Double Read
					VISIT 8	21NOV2017	8:08	2	Double Read
					VISIT 11	01DEC2020	9:58	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04SEP2015	8:34	0	Double Read
					VISIT 3A	30NOV2015	13:57	0	Double Read
					VISIT 4	08JAN2016	9:35	0	Double Read
					VISIT 6	18MAY2016	8:50	0	Double Read
					VISIT 7	22NOV2016	8:13	0	Double Read
					VISIT 8	21NOV2017	8:08	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		VISIT 11	01DEC2020	9:58	0	Double Read
					Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
					VISIT 7	22NOV2016	8:13		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
					Baseline	04SEP2015	8:34	N	Double Read
					VISIT 3A	30NOV2015	13:57	N	Double Read
					VISIT 4	08JAN2016	9:35	N	Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	22NOV2016	8:13	N	Double Read
					VISIT 8	21NOV2017	8:08	N	Double Read
					VISIT 11	01DEC2020	9:58	N	Double Read
					Baseline	04SEP2015	8:34	N	Double Read
					VISIT 3A	30NOV2015	13:57	N	Double Read
					VISIT 4	08JAN2016	9:35	N	Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
					VISIT 7	22NOV2016	8:13	N	Double Read
					VISIT 8	21NOV2017	8:08	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	21NOV2017	8:08	N	Double Read
					VISIT 11	01DEC2020	9:58	N	Double Read
Relevant scoliosis	5_S		General		Baseline	04SEP2015	8:34	N	Double Read
					VISIT 3A	30NOV2015	13:57	N	Double Read
					VISIT 4	08JAN2016	9:35	N	Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
					VISIT 7	22NOV2016	8:13	N	Double Read
					VISIT 8	21NOV2017	8:08	N	Double Read
					VISIT 11	01DEC2020	9:58	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	04SEP2015	8:34	N	Double Read
					VISIT 3A	30NOV2015	13:57	N	Double Read
					VISIT 4	08JAN2016	9:35	N	Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
					VISIT 7	22NOV2016	8:13	N	Double Read
					VISIT 8	21NOV2017	8:08	N	Double Read
					VISIT 11	01DEC2020	9:58	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	04SEP2015	8:34	N	Double Read
					VISIT 3A	30NOV2015	13:57	N	Double Read
					VISIT 4	08JAN2016	9:35	N	Double Read
					VISIT 6	18MAY2016	8:50	N	Double Read
					VISIT 7	22NOV2016	8:13	N	Double Read
					VISIT 8	21NOV2017	8:08	N	Double Read
					VISIT 11	01DEC2020	9:58	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	04SEP2015	8:34	60.72704	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	30NOV2015	13:57	61.90304	Double Read
					VISIT 4	08JAN2016	9:35	66.4512	Double Read
					VISIT 6	18MAY2016	8:50	63.48544	Double Read
					VISIT 7	22NOV2016	8:13	67.892	Double Read
					VISIT 8	21NOV2017	8:08	63.0024	Double Read
					VISIT 11	01DEC2020	9:58	65.3464	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	04SEP2015	8:34	65.84352	Double Read
					VISIT 3A	30NOV2015	13:57	58.0552	Double Read
					VISIT 4	08JAN2016	9:35	57.73776	Double Read
					VISIT 6	18MAY2016	8:50	62.21952	Double Read
					VISIT 7	22NOV2016	8:13	62.3936	Double Read
					VISIT 8	21NOV2017	8:08	59.2032	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	01DEC2020	9:58	67.01104	Double Read
					VISIT 3A	30NOV2015	13:57		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 8	21NOV2017	8:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	01DEC2020	9:58		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	04SEP2015	8:34	lower	Double Read
					VISIT 3A	30NOV2015	13:57	equal	Double Read
					VISIT 4	08JAN2016	9:35	equal	Double Read
					VISIT 6	18MAY2016	8:50	equal	Double Read
					VISIT 7	22NOV2016	8:13	lower	Double Read
					VISIT 8	21NOV2017	8:08	equal	Double Read
					VISIT 11	01DEC2020	9:58	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	04SEP2015	8:34	6.3092984542	Double Read
					VISIT 3A	30NOV2015	13:57	3.2737829115	Double Read
					VISIT 4	08JAN2016	9:35	6.7521657890	Double Read
					VISIT 6	18MAY2016	8:50	9.1586003057	Double Read
					VISIT 7	22NOV2016	8:13	4.1107525055	Double Read
					VISIT 8	21NOV2017	8:08	6.3780533378	Double Read
					VISIT 11	01DEC2020	9:58	2.3376728384	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	04SEP2015	8:34	10.1919483608	Double Read
					VISIT 3A	30NOV2015	13:57	7.73179548155	Double Read
					VISIT 4	08JAN2016	9:35	8.29959571938	Double Read
					VISIT 6	18MAY2016	8:50	8.44475624257	Double Read
					VISIT 7	22NOV2016	8:13	8.35739765585	Double Read
					VISIT 8	21NOV2017	8:08	12.813541702	Double Read
					VISIT 11	01DEC2020	9:58	9.20672668592	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	04SEP2015	8:34	11007.5	Double Read
					VISIT 3A	30NOV2015	13:57	10415.5	Double Read
					VISIT 4	08JAN2016	9:35	10275.0	Double Read
					VISIT 6	18MAY2016	8:50	10850.5	Double Read
					VISIT 7	22NOV2016	8:13	10116.5	Double Read
					VISIT 8	21NOV2017	8:08	7201.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1201 Age=55 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 11	01DEC2020	9:58	11539.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	04SEP2015	8:34	15248.5	Double Read
					VISIT 3A	30NOV2015	13:57	14057.0	Double Read
					VISIT 4	08JAN2016	9:35	13816.0	Double Read
					VISIT 6	18MAY2016	8:50	14586.5	Double Read
					VISIT 7	22NOV2016	8:13	14172.0	Double Read
					VISIT 8	21NOV2017	8:08	10714.5	Double Read
					VISIT 11	01DEC2020	9:58	13025.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	04SEP2015	8:34		Double Read
					VISIT 3A	30NOV2015	13:57		Double Read
					VISIT 4	08JAN2016	9:35		Double Read
					VISIT 6	18MAY2016	8:50		Double Read
					VISIT 7	22NOV2016	8:13		Double Read
					VISIT 8	21NOV2017	8:08		Double Read
					VISIT 11	01DEC2020	9:58		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1202 Age=59 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	02OCT2015	11:13	4	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	02OCT2015	11:13	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	02OCT2015	11:13	4	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	02OCT2015	11:13	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	02OCT2015	11:13	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	02OCT2015	11:13	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		Baseline	02OCT2015	11:13	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		Baseline	02OCT2015	11:13	N	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	02OCT2015	11:13	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	02OCT2015	11:13	N	Double Read
Fracture	4_5		General		Baseline	02OCT2015	11:13	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	02OCT2015	11:13	12.995	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	02OCT2015	11:13	16.745	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	02OCT2015	11:13	14.14	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1202 Age=59 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	02OCT2015	11:13	7.429285	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	02OCT2015	11:13	11.44495	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	02OCT2015	11:13	10.65545	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	02OCT2015	11:13	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	02OCT2015	11:13	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	02OCT2015	11:13	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	02OCT2015	11:13	N	Double Read
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	02OCT2015	11:13	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	02OCT2015	11:13	N	Double Read
Normal lordotic LS	4_5		General		Baseline	02OCT2015	11:13	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	02OCT2015	11:13	0	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	02OCT2015	11:13	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1202 Age=59 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	02OCT2015	11:13	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		Baseline	02OCT2015	11:13	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		Baseline	02OCT2015	11:13	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	02OCT2015	11:13	N	Double Read
Relevant scoliosis	4_5		General		Baseline	02OCT2015	11:13	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	02OCT2015	11:13	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	02OCT2015	11:13	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	02OCT2015	11:13	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	02OCT2015	11:13		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	02OCT2015	11:13	52.374336	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	02OCT2015	11:13		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	02OCT2015	11:13		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	02OCT2015	11:13	60.32304	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	02OCT2015	11:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1202 Age=59 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	02OCT2015	11:13		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	02OCT2015	11:13	54.08624	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	02OCT2015	11:13		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	02OCT2015	11:13		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	02OCT2015	11:13		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	02OCT2015	11:13		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	02OCT2015	11:13		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	02OCT2015	11:13	higher	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	02OCT2015	11:13		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	02OCT2015	11:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1202 Age=59 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	02OCT2015	11:13	higher	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	02OCT2015	11:13		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	02OCT2015	11:13		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	02OCT2015	11:13		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	02OCT2015	11:13		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	02OCT2015	11:13		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	02OCT2015	11:13	6.31361304569	Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	02OCT2015	11:13		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	02OCT2015	11:13		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	02OCT2015	11:13	9.06109733311	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	02OCT2015	11:13		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	02OCT2015	11:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=12/1202 Age=59 Sex=Male Actual Treatment=

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	02OCT2015	11:13	6.02762018005	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	02OCT2015	11:13		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	02OCT2015	11:13		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	02OCT2015	11:13	10976.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	02OCT2015	11:13		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	02OCT2015	11:13		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	02OCT2015	11:13	16518.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	02OCT2015	11:13		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	02OCT2015	11:13		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	02OCT2015	11:13	14814.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	02OCT2015	11:13		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S	4_5	Central Disc		Baseline	23APR2015	11:44	3	Double Read
					VISIT 3A	28JUL2015	11:44	4	Double Read
					VISIT 4	11SEP2015	14:39	4	Double Read
					VISIT 6	11JAN2016	14:10	3	Double Read
					VISIT 7	20JUL2016	14:12	3	Double Read
					VISIT 8	28JUN2017	16:16	3	Double Read
					VISIT 11	24JUN2020	15:37	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	23APR2015	11:44	2	Double Read
					VISIT 3A	28JUL2015	11:44	3	Double Read
					VISIT 4	11SEP2015	14:39	3	Double Read
					VISIT 6	11JAN2016	14:10	3	Double Read
					VISIT 7	20JUL2016	14:12	3	Double Read
					VISIT 8	28JUN2017	16:16	3	Double Read
					VISIT 11	24JUN2020	15:37	3	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S	4_5	Central Disc		Baseline	23APR2015	11:44	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S	4_5	Central Disc		VISIT 3A	28JUL2015	11:44	N	Double Read
					VISIT 4	11SEP2015	14:39	N	Double Read
					VISIT 6	11JAN2016	14:10	N	Double Read
					VISIT 7	20JUL2016	14:12	N	Double Read
					VISIT 8	28JUN2017	16:16	N	Double Read
					VISIT 11	24JUN2020	15:37	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	23APR2015	11:44	N	Double Read
					VISIT 3A	28JUL2015	11:44	N	Double Read
					VISIT 4	11SEP2015	14:39	N	Double Read
					VISIT 6	11JAN2016	14:10	N	Double Read
					VISIT 7	20JUL2016	14:12	N	Double Read
					VISIT 8	28JUN2017	16:16	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S	4_5	Caudal Disc		VISIT 11	24JUN2020	15:37	N	Double Read
					Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
Dorsal disc extrusion (Central Disc)	5_S	4_5	Central Disc		VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
					Baseline	23APR2015	11:44	Y	Double Read
					VISIT 3A	28JUL2015	11:44	Y	Double Read
					VISIT 4	11SEP2015	14:39	Y	Double Read
					VISIT 6	11JAN2016	14:10	Y	Double Read
Dorsal disc extrusion (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 7	20JUL2016	14:12	Y	Double Read
					VISIT 8	28JUN2017	16:16	N	Double Read
					VISIT 11	24JUN2020	15:37	N	Double Read
					Baseline	23APR2015	11:44	N	Double Read
					VISIT 3A	28JUL2015	11:44	N	Double Read
					VISIT 4	11SEP2015	14:39	N	Double Read
					VISIT 6	11JAN2016	14:10	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 7	20JUL2016	14:12	N	Double Read
					VISIT 8	28JUN2017	16:16	N	Double Read
					VISIT 11	24JUN2020	15:37	N	Double Read
Extradiscal fluid collection	5_S	4_5	General		Baseline	23APR2015	11:44	N	Double Read
					VISIT 3A	28JUL2015	11:44	N	Double Read
					VISIT 4	11SEP2015	14:39	N	Double Read
					VISIT 6	11JAN2016	14:10	N	Double Read
					VISIT 7	20JUL2016	14:12	N	Double Read
					VISIT 8	28JUN2017	16:16	N	Double Read
					VISIT 11	24JUN2020	15:37	N	Double Read
Fracture	5_S	4_5	General		Baseline	23APR2015	11:44	N	Double Read
					VISIT 3A	28JUL2015	11:44	N	Double Read
					VISIT 4	11SEP2015	14:39	N	Double Read
					VISIT 6	11JAN2016	14:10	N	Double Read
					VISIT 7	20JUL2016	14:12	N	Double Read
					VISIT 8	28JUN2017	16:16	N	Double Read
					VISIT 11	24JUN2020	15:37	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	23APR2015	11:44	11.895	Double Read
					VISIT 3A	28JUL2015	11:44	12.35	Double Read
					VISIT 4	11SEP2015	14:39	13.14	Double Read
					VISIT 6	11JAN2016	14:10	12.145	Double Read
					VISIT 7	20JUL2016	14:12	11.925	Double Read
					VISIT 8	28JUN2017	16:16	12.55	Double Read
					VISIT 11	24JUN2020	15:37	12.71	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	23APR2015	11:44	11.49	Double Read
					VISIT 3A	28JUL2015	11:44	12.195	Double Read
					VISIT 4	11SEP2015	14:39	13.48	Double Read
					VISIT 6	11JAN2016	14:10	13.56	Double Read
					VISIT 7	20JUL2016	14:12	14.11	Double Read
					VISIT 8	28JUN2017	16:16	13.945	Double Read
					VISIT 11	24JUN2020	15:37	13.315	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	23APR2015	11:44	7.006525	Double Read
					VISIT 3A	28JUL2015	11:44	6.83301	Double Read
					VISIT 4	11SEP2015	14:39	7.015405	Double Read
					VISIT 6	11JAN2016	14:10	6.907205	Double Read
					VISIT 7	20JUL2016	14:12	6.878405	Double Read
					VISIT 8	28JUN2017	16:16	6.526455	Double Read
					VISIT 11	24JUN2020	15:37	6.89109	Double Read
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	23APR2015	11:44	9.322705	Double Read
					VISIT 3A	28JUL2015	11:44	9.372395	Double Read
					VISIT 4	11SEP2015	14:39	9.27874	Double Read
					VISIT 6	11JAN2016	14:10	9.187695	Double Read
					VISIT 7	20JUL2016	14:12	9.93183	Double Read
					VISIT 8	28JUN2017	16:16	9.47435	Double Read
					VISIT 11	24JUN2020	15:37	10.66825	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S	4_5	Central Disc		Baseline	23APR2015	11:44	N	Double Read
					VISIT 3A	28JUL2015	11:44	N	Double Read
					VISIT 4	11SEP2015	14:39	N	Double Read
					VISIT 6	11JAN2016	14:10	N	Double Read
					VISIT 7	20JUL2016	14:12	N	Double Read
					VISIT 8	28JUN2017	16:16	N	Double Read
					VISIT 11	24JUN2020	15:37	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	23APR2015	11:44	N	Double Read
					VISIT 3A	28JUL2015	11:44	N	Double Read
					VISIT 4	11SEP2015	14:39	N	Double Read
					VISIT 6	11JAN2016	14:10	N	Double Read
					VISIT 7	20JUL2016	14:12	N	Double Read
					VISIT 8	28JUN2017	16:16	N	Double Read
					VISIT 11	24JUN2020	15:37	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S	4_5	Central Disc		Baseline	23APR2015	11:44	N	Double Read
					VISIT 3A	28JUL2015	11:44	N	Double Read
					VISIT 4	11SEP2015	14:39	N	Double Read
					VISIT 6	11JAN2016	14:10	N	Double Read
					VISIT 7	20JUL2016	14:12	N	Double Read
					VISIT 8	28JUN2017	16:16	N	Double Read
					VISIT 11	24JUN2020	15:37	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	23APR2015	11:44	N	Double Read
					VISIT 3A	28JUL2015	11:44	N	Double Read
					VISIT 4	11SEP2015	14:39	N	Double Read
					VISIT 6	11JAN2016	14:10	N	Double Read
					VISIT 7	20JUL2016	14:12	N	Double Read
					VISIT 8	28JUN2017	16:16	N	Double Read
					VISIT 11	24JUN2020	15:37	N	Double Read
Normal lordotic LS	5_S	4_5	General		Baseline	23APR2015	11:44	Y	Double Read
					VISIT 3A	28JUL2015	11:44	Y	Double Read
					VISIT 4	11SEP2015	14:39	Y	Double Read
					VISIT 6	11JAN2016	14:10	Y	Double Read
					VISIT 7	20JUL2016	14:12	Y	Double Read
					VISIT 8	28JUN2017	16:16	Y	Double Read
					VISIT 11	24JUN2020	15:37	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S	4_5	Central Disc		Baseline	23APR2015	11:44	0	Double Read
					VISIT 3A	28JUL2015	11:44	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S	4_5	Central Disc		VISIT 4	11SEP2015	14:39	0	Double Read
					VISIT 6	11JAN2016	14:10	0	Double Read
					VISIT 7	20JUL2016	14:12	0	Double Read
					VISIT 8	28JUN2017	16:16	0	Double Read
					VISIT 11	24JUN2020	15:37	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	23APR2015	11:44	0	Double Read
					VISIT 3A	28JUL2015	11:44	0	Double Read
					VISIT 4	11SEP2015	14:39	0	Double Read
					VISIT 6	11JAN2016	14:10	0	Double Read
					VISIT 7	20JUL2016	14:12	2	Double Read
					VISIT 8	28JUN2017	16:16	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S	4_5	Caudal Disc		VISIT 11	24JUN2020	15:37	0	Double Read
					Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
Protruding osteophyte (Central Disc)	5_S	4_5	Central Disc		VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37	N	Double Read
					Baseline	23APR2015	11:44	N	Double Read
					VISIT 3A	28JUL2015	11:44	N	Double Read
					VISIT 4	11SEP2015	14:39	N	Double Read
					VISIT 6	11JAN2016	14:10	N	Double Read
Protruding osteophyte (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 7	20JUL2016	14:12	N	Double Read
					VISIT 8	28JUN2017	16:16	N	Double Read
					VISIT 11	24JUN2020	15:37	N	Double Read
					Baseline	23APR2015	11:44	N	Double Read
					VISIT 3A	28JUL2015	11:44	N	Double Read
					VISIT 4	11SEP2015	14:39	N	Double Read
					VISIT 6	11JAN2016	14:10	N	Double Read
					VISIT 7	20JUL2016	14:12	N	Double Read
					VISIT 8	28JUN2017	16:16	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		VISIT 8	28JUN2017	16:16	N	Double Read
					VISIT 11	24JUN2020	15:37	N	Double Read
Relevant scoliosis	5_S	4_5	General		Baseline	23APR2015	11:44	N	Double Read
					VISIT 3A	28JUL2015	11:44	N	Double Read
					VISIT 4	11SEP2015	14:39	N	Double Read
					VISIT 6	11JAN2016	14:10	N	Double Read
					VISIT 7	20JUL2016	14:12	N	Double Read
					VISIT 8	28JUN2017	16:16	N	Double Read
					VISIT 11	24JUN2020	15:37	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S	4_5	Central Disc		Baseline	23APR2015	11:44	N	Double Read
					VISIT 3A	28JUL2015	11:44	N	Double Read
					VISIT 4	11SEP2015	14:39	N	Double Read
					VISIT 6	11JAN2016	14:10	N	Double Read
					VISIT 7	20JUL2016	14:12	N	Double Read
					VISIT 8	28JUN2017	16:16	N	Double Read
					VISIT 11	24JUN2020	15:37	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	23APR2015	11:44	N	Double Read
					VISIT 3A	28JUL2015	11:44	N	Double Read
					VISIT 4	11SEP2015	14:39	N	Double Read
					VISIT 6	11JAN2016	14:10	N	Double Read
					VISIT 7	20JUL2016	14:12	N	Double Read
					VISIT 8	28JUN2017	16:16	N	Double Read
					VISIT 11	24JUN2020	15:37	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	23APR2015	11:44	64.44144	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	VISIT 3A	28JUL2015	11:44	62.94304	Double Read
					VISIT 4	11SEP2015	14:39	66.1584	Double Read
					VISIT 6	11JAN2016	14:10	73.3928	Double Read
					VISIT 7	20JUL2016	14:12	70.7312	Double Read
					VISIT 8	28JUN2017	16:16	69.77936	Double Read
					VISIT 11	24JUN2020	15:37	65.00736	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
T2 (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
T2 (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	23APR2015	11:44	69.31808	Double Read
					VISIT 3A	28JUL2015	11:44	75.72816	Double Read
					VISIT 4	11SEP2015	14:39	78.23024	Double Read
					VISIT 6	11JAN2016	14:10	71.77888	Double Read
					VISIT 7	20JUL2016	14:12	76.79872	Double Read
					VISIT 8	28JUN2017	16:16	75.77888	Double Read
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	VISIT 11	24JUN2020	15:37	73.84656	Double Read
					VISIT 3A	28JUL2015	11:44		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S	4_5	Central Disc		Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		VISIT 11	24JUN2020	15:37		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	23APR2015	11:44	lower	Double Read
					VISIT 3A	28JUL2015	11:44	lower	Double Read
					VISIT 4	11SEP2015	14:39	lower	Double Read
					VISIT 6	11JAN2016	14:10	lower	Double Read
					VISIT 7	20JUL2016	14:12	lower	Double Read
					VISIT 8	28JUN2017	16:16	lower	Double Read
					VISIT 11	24JUN2020	15:37	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44	lower	Double Read
					VISIT 4	11SEP2015	14:39	lower	Double Read
					VISIT 6	11JAN2016	14:10	lower	Double Read
					VISIT 7	20JUL2016	14:12	lower	Double Read
					VISIT 8	28JUN2017	16:16	lower	Double Read
					VISIT 11	24JUN2020	15:37	equal	Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S	4_5	Central Disc		Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S	4_5	Central Disc		VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	23APR2015	11:44	7.60621029386	Double Read
					VISIT 3A	28JUL2015	11:44	8.49638185834	Double Read
					VISIT 4	11SEP2015	14:39	9.65592661798	Double Read
					VISIT 6	11JAN2016	14:10	7.3797248174	Double Read
					VISIT 7	20JUL2016	14:12	6.30929845422	Double Read
					VISIT 8	28JUN2017	16:16	7.39291319858	Double Read
					VISIT 11	24JUN2020	15:37	6.06927127569	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	23APR2015	11:44	6.8739052148	Double Read
					VISIT 3A	28JUL2015	11:44	5.0714319687	Double Read
					VISIT 4	11SEP2015	14:39	3.8861491421	Double Read
					VISIT 6	11JAN2016	14:10	10.366529641	Double Read
					VISIT 7	20JUL2016	14:12	9.1821912689	Double Read
					VISIT 8	28JUN2017	16:16	1.9272023101	Double Read
					VISIT 11	24JUN2020	15:37	4.7335960591	Double Read
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	23APR2015	11:44	10424.5	Double Read
					VISIT 3A	28JUL2015	11:44	10360.5	Double Read
					VISIT 4	11SEP2015	14:39	10800.5	Double Read
					VISIT 6	11JAN2016	14:10	10364.5	Double Read
					VISIT 7	20JUL2016	14:12	9872.0	Double Read
					VISIT 8	28JUN2017	16:16	10101.5	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1301 Age=46 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	VISIT 11	24JUN2020	15:37	10283.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	23APR2015	11:44	11595.5	Double Read
					VISIT 3A	28JUL2015	11:44	12886.0	Double Read
					VISIT 4	11SEP2015	14:39	14168.0	Double Read
					VISIT 6	11JAN2016	14:10	13611.5	Double Read
					VISIT 7	20JUL2016	14:12	13029.0	Double Read
					VISIT 8	28JUN2017	16:16	13694.0	Double Read
					VISIT 11	24JUN2020	15:37	14010.5	Double Read
Volume (mm^3) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	23APR2015	11:44		Double Read
					VISIT 3A	28JUL2015	11:44		Double Read
					VISIT 4	11SEP2015	14:39		Double Read
					VISIT 6	11JAN2016	14:10		Double Read
					VISIT 7	20JUL2016	14:12		Double Read
					VISIT 8	28JUN2017	16:16		Double Read
					VISIT 11	24JUN2020	15:37		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	4_5		Caudal Disc		Baseline	11MAY2015	17:34	4	Double Read
					VISIT 3A	28JUL2015	13:45	4	Double Read
					VISIT 4	11SEP2015	13:08	4	Double Read
					VISIT 6	11JAN2016	16:08	3	Double Read
					VISIT 7	19JUL2016	14:56	4	Double Read
					VISIT 8	19JUL2017	15:25	4	Double Read
					VISIT 11	01JUL2020	16:07	4	Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	4_5		Central Disc		Baseline	11MAY2015	17:34	3	Double Read
					VISIT 3A	28JUL2015	13:45	3	Double Read
					VISIT 4	11SEP2015	13:08	3	Double Read
					VISIT 6	11JAN2016	16:08	3	Double Read
					VISIT 7	19JUL2016	14:56	3	Double Read
					VISIT 8	19JUL2017	15:25	3	Double Read
					VISIT 11	01JUL2020	16:07	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	11MAY2015	17:34	2	Double Read
					VISIT 3A	28JUL2015	13:45	2	Double Read
					VISIT 4	11SEP2015	13:08	2	Double Read
					VISIT 6	11JAN2016	16:08	2	Double Read
					VISIT 7	19JUL2016	14:56	2	Double Read
					VISIT 8	19JUL2017	15:25	2	Double Read
					VISIT 11	01JUL2020	16:07	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	4_5		Caudal Disc		Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		Baseline	11MAY2015	17:34	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	4_5		Central Disc		VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
Dorsal disc extrusion (Caudal Disc)	4_5		Caudal Disc		VISIT 11	01JUL2020	16:07	N	Double Read
					Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read
Dorsal disc extrusion (Central Disc)	4_5		Central Disc		VISIT 8	19JUL2017	15:25	Y	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read
					Baseline	11MAY2015	17:34	Y	Double Read
					VISIT 3A	28JUL2015	13:45	Y	Double Read
					VISIT 4	11SEP2015	13:08	Y	Double Read
					VISIT 6	11JAN2016	16:08	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	Y	Double Read
					Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read
Extradiscal fluid collection	4_5		General		Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read
Fracture	4_5		General		Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	11MAY2015	17:34	12.865	Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08	13.835	Double Read
					VISIT 6	11JAN2016	16:08	13.895	Double Read
					VISIT 7	19JUL2016	14:56	13.295	Double Read
					VISIT 8	19JUL2017	15:25	14.735	Double Read
					VISIT 11	01JUL2020	16:07	13.425	Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	11MAY2015	17:34	13.405	Double Read
					VISIT 3A	28JUL2015	13:45	12.2	Double Read
					VISIT 4	11SEP2015	13:08	11.21	Double Read
					VISIT 6	11JAN2016	16:08	11.74	Double Read
					VISIT 7	19JUL2016	14:56	11.91	Double Read
					VISIT 8	19JUL2017	15:25	11.32	Double Read
					VISIT 11	01JUL2020	16:07	13.41	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	11MAY2015	17:34	13.865	Double Read
					VISIT 3A	28JUL2015	13:45	12.98	Double Read
					VISIT 4	11SEP2015	13:08	13.49	Double Read
					VISIT 6	11JAN2016	16:08	13.16	Double Read
					VISIT 7	19JUL2016	14:56	13.79	Double Read
					VISIT 8	19JUL2017	15:25	14.4	Double Read
					VISIT 11	01JUL2020	16:07	13.48	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	11MAY2015	17:34	7.123485	Double Read
					VISIT 3A	28JUL2015	13:45	6.495965	Double Read
					VISIT 4	11SEP2015	13:08	7.5875	Double Read
					VISIT 6	11JAN2016	16:08	6.76061	Double Read
					VISIT 7	19JUL2016	14:56	5.85395	Double Read
					VISIT 8	19JUL2017	15:25	6.641115	Double Read
					VISIT 11	01JUL2020	16:07	6.41229	Double Read
Height manual (mm) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	11MAY2015	17:34	10.73785	Double Read
					VISIT 3A	28JUL2015	13:45	9.39432	Double Read
					VISIT 4	11SEP2015	13:08	9.331555	Double Read
					VISIT 6	11JAN2016	16:08	9.238915	Double Read
					VISIT 7	19JUL2016	14:56	8.40123	Double Read
					VISIT 8	19JUL2017	15:25	8.072095	Double Read
					VISIT 11	01JUL2020	16:07	6.07242	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	11MAY2015	17:34	11.96145	Double Read
					VISIT 3A	28JUL2015	13:45	11.3423	Double Read
					VISIT 4	11SEP2015	13:08	12.43225	Double Read
					VISIT 6	11JAN2016	16:08	11.13855	Double Read
					VISIT 7	19JUL2016	14:56	11.7506	Double Read
					VISIT 8	19JUL2017	15:25	12.1388	Double Read
					VISIT 11	01JUL2020	16:07	11.4106	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	4_5		Caudal Disc		Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	4_5		Central Disc		Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	4_5		Caudal Disc		Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	4_5		Central Disc		Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read
Normal lordotic LS	4_5		General		Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	4_5		Caudal Disc		Baseline	11MAY2015	17:34	2	Double Read
					VISIT 3A	28JUL2015	13:45	2	Double Read
					VISIT 4	11SEP2015	13:08	2	Double Read
					VISIT 6	11JAN2016	16:08	2	Double Read
					VISIT 7	19JUL2016	14:56	2	Double Read
					VISIT 8	19JUL2017	15:25	2	Double Read
					VISIT 11	01JUL2020	16:07	2	Double Read
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		Baseline	11MAY2015	17:34	0	Double Read
					VISIT 3A	28JUL2015	13:45	2	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	4_5		Central Disc		VISIT 4	11SEP2015	13:08	0	Double Read
					VISIT 6	11JAN2016	16:08	2	Double Read
					VISIT 7	19JUL2016	14:56	2	Double Read
					VISIT 8	19JUL2017	15:25	2	Double Read
					VISIT 11	01JUL2020	16:07	2	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	11MAY2015	17:34	0	Double Read
					VISIT 3A	28JUL2015	13:45	0	Double Read
					VISIT 4	11SEP2015	13:08	0	Double Read
					VISIT 6	11JAN2016	16:08	0	Double Read
					VISIT 7	19JUL2016	14:56	0	Double Read
					VISIT 8	19JUL2017	15:25	0	Double Read
Protruding osteophyte (Caudal Disc)	4_5		Caudal Disc		VISIT 11	01JUL2020	16:07	0	Double Read
					Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read
Protruding osteophyte (Central Disc)	4_5		Central Disc		VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read
					Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read
Relevant scoliosis	4_5		General		Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	4_5		Caudal Disc		Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	4_5		Central Disc		Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	4_5		Cranial Disc, not treated		Baseline	11MAY2015	17:34	N	Double Read
					VISIT 3A	28JUL2015	13:45	N	Double Read
					VISIT 4	11SEP2015	13:08	N	Double Read
					VISIT 6	11JAN2016	16:08	N	Double Read
					VISIT 7	19JUL2016	14:56	N	Double Read
					VISIT 8	19JUL2017	15:25	N	Double Read
					VISIT 11	01JUL2020	16:07	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	11MAY2015	17:34	75.26832	Double Read
					VISIT 3A	28JUL2015	13:45	72.84064	Double Read
					VISIT 4	11SEP2015	13:08	74.36096	Double Read
					VISIT 6	11JAN2016	16:08	70.03024	Double Read
					VISIT 7	19JUL2016	14:56	78.9792	Double Read
					VISIT 8	19JUL2017	15:25	73.12192	Double Read
					VISIT 11	01JUL2020	16:07	73.11536	Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	11MAY2015	17:34	77.86416	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	28JUL2015	13:45	72.27888	Double Read
					VISIT 4	11SEP2015	13:08	72.7952	Double Read
					VISIT 6	11JAN2016	16:08	70.3032	Double Read
					VISIT 7	19JUL2016	14:56	67.29312	Double Read
					VISIT 8	19JUL2017	15:25	70.31488	Double Read
					VISIT 11	01JUL2020	16:07	70.25792	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	VISIT 11	01JUL2020	16:07		Double Read
					Baseline	11MAY2015	17:34	106.99648	Double Read
					VISIT 3A	28JUL2015	13:45	104.77152	Double Read
					VISIT 4	11SEP2015	13:08	102.41568	Double Read
					VISIT 6	11JAN2016	16:08	104.60784	Double Read
					VISIT 7	19JUL2016	14:56	103.63376	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 8	19JUL2017	15:25	98.97648	Double Read
					VISIT 11	01JUL2020	16:07	91.2	Double Read
					Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	4_5		Caudal Disc		Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	4_5		Central Disc		Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	11MAY2015	17:34	higher	Double Read
					VISIT 3A	28JUL2015	13:45	higher	Double Read
					VISIT 4	11SEP2015	13:08	higher	Double Read
					VISIT 6	11JAN2016	16:08	equal	Double Read
					VISIT 7	19JUL2016	14:56	equal	Double Read
					VISIT 8	19JUL2017	15:25	higher	Double Read
					VISIT 11	01JUL2020	16:07	higher	Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	4_5		Caudal Disc		VISIT 11	01JUL2020	16:07		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	4_5		Central Disc		Baseline	11MAY2015	17:34	lower	Double Read
					VISIT 3A	28JUL2015	13:45	lower	Double Read
					VISIT 4	11SEP2015	13:08	lower	Double Read
					VISIT 6	11JAN2016	16:08	lower	Double Read
					VISIT 7	19JUL2016	14:56	lower	Double Read
					VISIT 8	19JUL2017	15:25	lower	Double Read
					VISIT 11	01JUL2020	16:07	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	4_5		Caudal Disc		Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	4_5		Central Disc		VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	4_5		Cranial Disc, not treated		Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	11MAY2015	17:34	9.6257312722	Double Read
					VISIT 3A	28JUL2015	13:45	9.8522167487	Double Read
					VISIT 4	11SEP2015	13:08	11.482928486	Double Read
					VISIT 6	11JAN2016	16:08	8.4070120604	Double Read
					VISIT 7	19JUL2016	14:56	8.5941362324	Double Read
					VISIT 8	19JUL2017	15:25	6.9644980465	Double Read
					VISIT 11	01JUL2020	16:07	8.5782232036	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read
T2_error (ms) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	11MAY2015	17:34	9.58043145915	Double Read
					VISIT 3A	28JUL2015	13:45	15.2377781553	Double Read
					VISIT 4	11SEP2015	13:08	15.5823339562	Double Read
					VISIT 6	11JAN2016	16:08	7.31817224392	Double Read
					VISIT 7	19JUL2016	14:56	8.13476473586	Double Read
					VISIT 8	19JUL2017	15:25	9.96735179208	Double Read
					VISIT 11	01JUL2020	16:07	8.17316120265	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	11MAY2015	17:34	1.9874299303	Double Read
					VISIT 3A	28JUL2015	13:45	2.8513198573	Double Read
					VISIT 4	11SEP2015	13:08	2.8007609988	Double Read
					VISIT 6	11JAN2016	16:08	4.8290402582	Double Read
					VISIT 7	19JUL2016	14:56	7.7572006115	Double Read
					VISIT 8	19JUL2017	15:25	10.818590113	Double Read
					VISIT 11	01JUL2020	16:07	2.3086257856	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	4_5		Caudal Disc	Anulus Fibrosus	Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	4_5		Caudal Disc	Complete Disc	Baseline	11MAY2015	17:34	13950.5	Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08	12941.5	Double Read
					VISIT 6	11JAN2016	16:08	12815.0	Double Read
					VISIT 7	19JUL2016	14:56	12804.0	Double Read
					VISIT 8	19JUL2017	15:25	12471.0	Double Read
					VISIT 11	01JUL2020	16:07	12037.5	Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	4_5		Caudal Disc	Nucleus Pulposus	Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	4_5		Central Disc	Anulus Fibrosus	Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	Baseline	11MAY2015	17:34	17255.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	4_5		Central Disc	Complete Disc	VISIT 3A	28JUL2015	13:45	14080.5	Double Read
					VISIT 4	11SEP2015	13:08	16861.5	Double Read
					VISIT 6	11JAN2016	16:08	15537.5	Double Read
					VISIT 7	19JUL2016	14:56	16874.5	Double Read
					VISIT 8	19JUL2017	15:25	15172.5	Double Read
					VISIT 11	01JUL2020	16:07	13592.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	4_5		Central Disc	Nucleus Pulposus	Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	4_5		Cranial Disc, not treated	Anulus Fibrosus	Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read
					VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	4_5		Cranial Disc, not treated	Complete Disc	Baseline	11MAY2015	17:34	20434.0	Double Read
					VISIT 3A	28JUL2015	13:45	17746.5	Double Read
					VISIT 4	11SEP2015	13:08	20580.0	Double Read
					VISIT 6	11JAN2016	16:08	19655.5	Double Read
					VISIT 7	19JUL2016	14:56	21164.0	Double Read
					VISIT 8	19JUL2017	15:25	21115.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	Baseline	11MAY2015	17:34		Double Read
					VISIT 3A	28JUL2015	13:45		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1302 Age=30 Sex=Male Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	4_5		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	11SEP2015	13:08		Double Read
					VISIT 6	11JAN2016	16:08		Double Read
					VISIT 7	19JUL2016	14:56		Double Read
					VISIT 8	19JUL2017	15:25		Double Read
					VISIT 11	01JUL2020	16:07		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1303 Age=31 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	25JUN2015	14:14	3	Double Read
					VISIT 4	26AUG2015	14:43	3	Double Read
					VISIT 6	14DEC2015	15:15	4	Double Read
					VISIT 7	06JUL2016	14:45	4	Double Read
					VISIT 8	12JUL2017	15:26	4	Double Read
					VISIT 11	03JUN2020	12:48	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25JUN2015	14:14	2	Double Read
					VISIT 4	26AUG2015	14:43	2	Double Read
					VISIT 6	14DEC2015	15:15	2	Double Read
					VISIT 7	06JUL2016	14:45	2	Double Read
					VISIT 8	12JUL2017	15:26	2	Double Read
					VISIT 11	03JUN2020	12:48	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	25JUN2015	14:14	N	Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15	N	Double Read
					VISIT 7	06JUL2016	14:45	N	Double Read
					VISIT 8	12JUL2017	15:26	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1303 Age=31 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 11	03JUN2020	12:48	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25JUN2015	14:14	N	Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15	N	Double Read
					VISIT 7	06JUL2016	14:45	N	Double Read
					VISIT 8	12JUL2017	15:26	N	Double Read
					VISIT 11	03JUN2020	12:48	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		Baseline	25JUN2015	14:14	Y	Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15	Y	Double Read
					VISIT 7	06JUL2016	14:45	Y	Double Read
					VISIT 8	12JUL2017	15:26	Y	Double Read
					VISIT 11	03JUN2020	12:48	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25JUN2015	14:14	N	Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15	N	Double Read
					VISIT 7	06JUL2016	14:45	N	Double Read
					VISIT 8	12JUL2017	15:26	N	Double Read
					VISIT 11	03JUN2020	12:48	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	25JUN2015	14:14	N	Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15	N	Double Read
					VISIT 7	06JUL2016	14:45	N	Double Read
					VISIT 8	12JUL2017	15:26	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1303 Age=31 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Extradiscal fluid collection	5_S		General		VISIT 11	03JUN2020	12:48	N	Double Read
Fracture	5_S		General		Baseline	25JUN2015	14:14	N	Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15	N	Double Read
					VISIT 7	06JUL2016	14:45	N	Double Read
					VISIT 8	12JUL2017	15:26	N	Double Read
					VISIT 11	03JUN2020	12:48	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25JUN2015	14:14	12.89	Double Read
					VISIT 4	26AUG2015	14:43	12.5	Double Read
					VISIT 6	14DEC2015	15:15	13.545	Double Read
					VISIT 7	06JUL2016	14:45	11.38	Double Read
					VISIT 8	12JUL2017	15:26	14.995	Double Read
					VISIT 11	03JUN2020	12:48	11.285	Double Read
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25JUN2015	14:14	16.485	Double Read
					VISIT 4	26AUG2015	14:43	16.695	Double Read
					VISIT 6	14DEC2015	15:15	16.0	Double Read
					VISIT 7	06JUL2016	14:45	15.455	Double Read
					VISIT 8	12JUL2017	15:26	16.555	Double Read
					VISIT 11	03JUN2020	12:48	16.28	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1303 Age=31 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25JUN2015	14:14	8.44888	Double Read
					VISIT 4	26AUG2015	14:43	6.583235	Double Read
					VISIT 6	14DEC2015	15:15	8.505885	Double Read
					VISIT 7	06JUL2016	14:45	8.347565	Double Read
					VISIT 8	12JUL2017	15:26	9.00181	Double Read
					VISIT 11	03JUN2020	12:48	8.44228	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25JUN2015	14:14	13.77935	Double Read
					VISIT 4	26AUG2015	14:43	12.4601	Double Read
					VISIT 6	14DEC2015	15:15	13.1896	Double Read
					VISIT 7	06JUL2016	14:45	12.42925	Double Read
					VISIT 8	12JUL2017	15:26	13.1581	Double Read
					VISIT 11	03JUN2020	12:48	13.39505	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	25JUN2015	14:14	N	Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15	N	Double Read
					VISIT 7	06JUL2016	14:45	N	Double Read
					VISIT 8	12JUL2017	15:26	N	Double Read
					VISIT 11	03JUN2020	12:48	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1303 Age=31 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25JUN2015	14:14	N	Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15	N	Double Read
					VISIT 7	06JUL2016	14:45	N	Double Read
					VISIT 8	12JUL2017	15:26	N	Double Read
					VISIT 11	03JUN2020	12:48	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	25JUN2015	14:14	N	Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15	N	Double Read
					VISIT 7	06JUL2016	14:45	N	Double Read
					VISIT 8	12JUL2017	15:26	N	Double Read
					VISIT 11	03JUN2020	12:48	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25JUN2015	14:14	N	Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15	N	Double Read
					VISIT 7	06JUL2016	14:45	N	Double Read
					VISIT 8	12JUL2017	15:26	N	Double Read
					VISIT 11	03JUN2020	12:48	N	Double Read
Normal lordotic LS	5_S		General		Baseline	25JUN2015	14:14	Y	Double Read
					VISIT 4	26AUG2015	14:43	Y	Double Read
					VISIT 6	14DEC2015	15:15	Y	Double Read
					VISIT 7	06JUL2016	14:45	Y	Double Read
					VISIT 8	12JUL2017	15:26	Y	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1303 Age=31 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Normal lordotic LS	5_S		General		VISIT 11	03JUN2020	12:48	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43	0	Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	25JUN2015	14:14	0	Double Read
					VISIT 4	26AUG2015	14:43	0	Double Read
					VISIT 6	14DEC2015	15:15	0	Double Read
					VISIT 7	06JUL2016	14:45	0	Double Read
					VISIT 8	12JUL2017	15:26	0	Double Read
					VISIT 11	03JUN2020	12:48	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25JUN2015	14:14	0	Double Read
					VISIT 4	26AUG2015	14:43	0	Double Read
					VISIT 6	14DEC2015	15:15	0	Double Read
					VISIT 7	06JUL2016	14:45	0	Double Read
					VISIT 8	12JUL2017	15:26	0	Double Read
					VISIT 11	03JUN2020	12:48	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	25JUN2015	14:14	N	Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15	N	Double Read
					VISIT 7	06JUL2016	14:45	N	Double Read
					VISIT 8	12JUL2017	15:26	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1303 Age=31 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Central Disc)	5_S		Central Disc		VISIT 11	03JUN2020	12:48	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25JUN2015	14:14	N	Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15	N	Double Read
					VISIT 7	06JUL2016	14:45	N	Double Read
					VISIT 8	12JUL2017	15:26	N	Double Read
					VISIT 11	03JUN2020	12:48	N	Double Read
Relevant scoliosis	5_S		General		Baseline	25JUN2015	14:14	N	Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15	N	Double Read
					VISIT 7	06JUL2016	14:45	N	Double Read
					VISIT 8	12JUL2017	15:26	N	Double Read
					VISIT 11	03JUN2020	12:48	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	25JUN2015	14:14	N	Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15	N	Double Read
					VISIT 7	06JUL2016	14:45	N	Double Read
					VISIT 8	12JUL2017	15:26	N	Double Read
					VISIT 11	03JUN2020	12:48	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	25JUN2015	14:14	N	Double Read
					VISIT 4	26AUG2015	14:43	N	Double Read
					VISIT 6	14DEC2015	15:15	N	Double Read
					VISIT 7	06JUL2016	14:45	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1303 Age=31 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	12JUL2017	15:26	N	Double Read
					VISIT 11	03JUN2020	12:48	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25JUN2015	14:14	70.29232	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1303 Age=31 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 4	26AUG2015	14:43	70.37936	Double Read
					VISIT 6	14DEC2015	15:15	69.31536	Double Read
					VISIT 7	06JUL2016	14:45	66.2888	Double Read
					VISIT 8	12JUL2017	15:26	66.90352	Double Read
					VISIT 11	03JUN2020	12:48	62.71552	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25JUN2015	14:14	97.75424	Double Read
					VISIT 4	26AUG2015	14:43	103.57856	Double Read
					VISIT 6	14DEC2015	15:15	95.91504	Double Read
					VISIT 7	06JUL2016	14:45	94.56368	Double Read
					VISIT 8	12JUL2017	15:26	97.07216	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	03JUN2020	12:48	91.9048	Double Read
					Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1303 Age=31 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1303 Age=31 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	25JUN2015	14:14	lower	Double Read
					VISIT 4	26AUG2015	14:43	lower	Double Read
					VISIT 6	14DEC2015	15:15	lower	Double Read
					VISIT 7	06JUL2016	14:45	lower	Double Read
					VISIT 8	12JUL2017	15:26	lower	Double Read
					VISIT 11	03JUN2020	12:48	lower	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1303 Age=31 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1303 Age=31 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25JUN2015	14:14	6.17179548157	Double Read
					VISIT 4	26AUG2015	14:43	6.62476643452	Double Read
					VISIT 6	14DEC2015	15:15	8.74808900968	Double Read
					VISIT 7	06JUL2016	14:45	5.48099881094	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1303 Age=31 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	12JUL2017	15:26	7.6590589434	Double Read
					VISIT 11	03JUN2020	12:48	5.9978053337	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25JUN2015	14:14	8.3800441651	Double Read
					VISIT 4	26AUG2015	14:43	5.4357057924	Double Read
					VISIT 6	14DEC2015	15:15	10.934968574	Double Read
					VISIT 7	06JUL2016	14:45	8.7201834550	Double Read
					VISIT 8	12JUL2017	15:26	10.947851197	Double Read
					VISIT 11	03JUN2020	12:48	2.9273517920	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1303 Age=31 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1303 Age=31 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	25JUN2015	14:14	11239.0	Double Read
					VISIT 4	26AUG2015	14:43	11292.0	Double Read
					VISIT 6	14DEC2015	15:15	10675.0	Double Read
					VISIT 7	06JUL2016	14:45	9918.0	Double Read
					VISIT 8	12JUL2017	15:26	11580.0	Double Read
					VISIT 11	03JUN2020	12:48	9186.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read
					VISIT 11	03JUN2020	12:48		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	25JUN2015	14:14	16838.0	Double Read
					VISIT 4	26AUG2015	14:43	18272.0	Double Read
					VISIT 6	14DEC2015	15:15	17569.0	Double Read
					VISIT 7	06JUL2016	14:45	16453.0	Double Read
					VISIT 8	12JUL2017	15:26	17611.0	Double Read
					VISIT 11	03JUN2020	12:48	17071.5	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	25JUN2015	14:14		Double Read
					VISIT 4	26AUG2015	14:43		Double Read
					VISIT 6	14DEC2015	15:15		Double Read
					VISIT 7	06JUL2016	14:45		Double Read
					VISIT 8	12JUL2017	15:26		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1303 Age=31 Sex=Male Actual Treatment=SC

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	03JUN2020	12:48		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S		Caudal Disc		Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S		Central Disc		Baseline	23JUN2015	13:36	4	Double Read
					VISIT 3A	16SEP2015	15:57	4	Double Read
					VISIT 4	02NOV2015	15:31	4	Double Read
					VISIT 6	21MAR2016	15:41	4	Double Read
					VISIT 7	14SEP2016	15:36	4	Double Read
					VISIT 8	06SEP2017	15:20	4	Double Read
					VISIT 11	02SEP2020	15:05	4	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	23JUN2015	13:36	2	Double Read
					VISIT 3A	16SEP2015	15:57	2	Double Read
					VISIT 4	02NOV2015	15:31	2	Double Read
					VISIT 6	21MAR2016	15:41	2	Double Read
					VISIT 7	14SEP2016	15:36	2	Double Read
					VISIT 8	06SEP2017	15:20	2	Double Read
					VISIT 11	02SEP2020	15:05	2	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S		Caudal Disc		Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		Baseline	23JUN2015	13:36	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S		Central Disc		VISIT 3A	16SEP2015	15:57	N	Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41	N	Double Read
					VISIT 7	14SEP2016	15:36	N	Double Read
					VISIT 8	06SEP2017	15:20	N	Double Read
					VISIT 11	02SEP2020	15:05	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	23JUN2015	13:36	N	Double Read
					VISIT 3A	16SEP2015	15:57	N	Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41	N	Double Read
					VISIT 7	14SEP2016	15:36	N	Double Read
					VISIT 8	06SEP2017	15:20	N	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S		Caudal Disc		VISIT 11	02SEP2020	15:05	N	Double Read
					Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
Dorsal disc extrusion (Central Disc)	5_S		Central Disc		VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
					Baseline	23JUN2015	13:36	Y	Double Read
					VISIT 3A	16SEP2015	15:57	Y	Double Read
					VISIT 4	02NOV2015	15:31	Y	Double Read
					VISIT 6	21MAR2016	15:41	Y	Double Read
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	14SEP2016	15:36	Y	Double Read
					VISIT 8	06SEP2017	15:20	Y	Double Read
					VISIT 11	02SEP2020	15:05	Y	Double Read
					Baseline	23JUN2015	13:36	N	Double Read
					VISIT 3A	16SEP2015	15:57	N	Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Dorsal disc extrusion (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 7	14SEP2016	15:36	N	Double Read
					VISIT 8	06SEP2017	15:20	N	Double Read
					VISIT 11	02SEP2020	15:05	N	Double Read
Extradiscal fluid collection	5_S		General		Baseline	23JUN2015	13:36	N	Double Read
					VISIT 3A	16SEP2015	15:57	N	Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41	N	Double Read
					VISIT 7	14SEP2016	15:36	N	Double Read
					VISIT 8	06SEP2017	15:20	N	Double Read
					VISIT 11	02SEP2020	15:05	N	Double Read
Fracture	5_S		General		Baseline	23JUN2015	13:36	N	Double Read
					VISIT 3A	16SEP2015	15:57	N	Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41	N	Double Read
					VISIT 7	14SEP2016	15:36	N	Double Read
					VISIT 8	06SEP2017	15:20	N	Double Read
					VISIT 11	02SEP2020	15:05	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	23JUN2015	13:36	13.03	Double Read
					VISIT 3A	16SEP2015	15:57	12.885	Double Read
					VISIT 4	02NOV2015	15:31	13.23	Double Read
					VISIT 6	21MAR2016	15:41	13.51	Double Read
					VISIT 7	14SEP2016	15:36	12.075	Double Read
					VISIT 8	06SEP2017	15:20	13.625	Double Read
					VISIT 11	02SEP2020	15:05	13.04	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height from Volume (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	23JUN2015	13:36	14.67	Double Read
					VISIT 3A	16SEP2015	15:57	15.435	Double Read
					VISIT 4	02NOV2015	15:31	15.13	Double Read
					VISIT 6	21MAR2016	15:41	15.325	Double Read
					VISIT 7	14SEP2016	15:36	15.1	Double Read
					VISIT 8	06SEP2017	15:20	15.36	Double Read
					VISIT 11	02SEP2020	15:05	14.77	Double Read
Height manual (mm) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	23JUN2015	13:36	8.417595	Double Read
					VISIT 3A	16SEP2015	15:57	7.906585	Double Read
					VISIT 4	02NOV2015	15:31	6.395635	Double Read
					VISIT 6	21MAR2016	15:41	6.98781	Double Read
					VISIT 7	14SEP2016	15:36	7.554905	Double Read
					VISIT 8	06SEP2017	15:20	8.15087	Double Read
					VISIT 11	02SEP2020	15:05	7.193535	Double Read
Height manual (mm) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	23JUN2015	13:36	13.9085	Double Read
					VISIT 3A	16SEP2015	15:57	13.1377	Double Read
					VISIT 4	02NOV2015	15:31	12.6171	Double Read
					VISIT 6	21MAR2016	15:41	13.5828	Double Read
					VISIT 7	14SEP2016	15:36	13.70825	Double Read
					VISIT 8	06SEP2017	15:20	12.675	Double Read
					VISIT 11	02SEP2020	15:05	13.3706	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S		Caudal Disc		Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S		Central Disc		Baseline	23JUN2015	13:36	N	Double Read
					VISIT 3A	16SEP2015	15:57	N	Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41	N	Double Read
					VISIT 7	14SEP2016	15:36	N	Double Read
					VISIT 8	06SEP2017	15:20	N	Double Read
					VISIT 11	02SEP2020	15:05	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	23JUN2015	13:36	N	Double Read
					VISIT 3A	16SEP2015	15:57	N	Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41	N	Double Read
					VISIT 7	14SEP2016	15:36	N	Double Read
					VISIT 8	06SEP2017	15:20	N	Double Read
					VISIT 11	02SEP2020	15:05	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S		Caudal Disc		Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
More than moderate degenerative spinal stenosis (Central Disc)	5_S		Central Disc		Baseline	23JUN2015	13:36	N	Double Read
					VISIT 3A	16SEP2015	15:57	N	Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41	N	Double Read
					VISIT 7	14SEP2016	15:36	N	Double Read
					VISIT 8	06SEP2017	15:20	N	Double Read
					VISIT 11	02SEP2020	15:05	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	23JUN2015	13:36	N	Double Read
					VISIT 3A	16SEP2015	15:57	N	Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41	N	Double Read
					VISIT 7	14SEP2016	15:36	N	Double Read
					VISIT 8	06SEP2017	15:20	N	Double Read
					VISIT 11	02SEP2020	15:05	N	Double Read
Normal lordotic LS	5_S		General		Baseline	23JUN2015	13:36	Y	Double Read
					VISIT 3A	16SEP2015	15:57	Y	Double Read
					VISIT 4	02NOV2015	15:31	Y	Double Read
					VISIT 6	21MAR2016	15:41	Y	Double Read
					VISIT 7	14SEP2016	15:36	Y	Double Read
					VISIT 8	06SEP2017	15:20	Y	Double Read
					VISIT 11	02SEP2020	15:05	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S		Caudal Disc		Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		Baseline	23JUN2015	13:36	0	Double Read
					VISIT 3A	16SEP2015	15:57	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Central Disc)	5_S		Central Disc		VISIT 4	02NOV2015	15:31	2	Double Read
					VISIT 6	21MAR2016	15:41	0	Double Read
					VISIT 7	14SEP2016	15:36	2	Double Read
					VISIT 8	06SEP2017	15:20	0	Double Read
					VISIT 11	02SEP2020	15:05	0	Double Read
Osteochondrosis grading (Modic) (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	23JUN2015	13:36	0	Double Read
					VISIT 3A	16SEP2015	15:57	0	Double Read
					VISIT 4	02NOV2015	15:31	0	Double Read
					VISIT 6	21MAR2016	15:41	0	Double Read
					VISIT 7	14SEP2016	15:36	0	Double Read
					VISIT 8	06SEP2017	15:20	0	Double Read
Protruding osteophyte (Caudal Disc)	5_S		Caudal Disc		Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
Protruding osteophyte (Central Disc)	5_S		Central Disc		Baseline	23JUN2015	13:36	N	Double Read
					VISIT 3A	16SEP2015	15:57	N	Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41	N	Double Read
					VISIT 7	14SEP2016	15:36	N	Double Read
					VISIT 8	06SEP2017	15:20	N	Double Read
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 11	02SEP2020	15:05	N	Double Read
					Baseline	23JUN2015	13:36	N	Double Read
					VISIT 3A	16SEP2015	15:57	N	Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41	N	Double Read
					VISIT 7	14SEP2016	15:36	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Protruding osteophyte (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		VISIT 8	06SEP2017	15:20	N	Double Read
					VISIT 11	02SEP2020	15:05	N	Double Read
Relevant scoliosis	5_S		General		Baseline	23JUN2015	13:36	N	Double Read
					VISIT 3A	16SEP2015	15:57	N	Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41	N	Double Read
					VISIT 7	14SEP2016	15:36	N	Double Read
					VISIT 8	06SEP2017	15:20	N	Double Read
					VISIT 11	02SEP2020	15:05	N	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S		Caudal Disc		Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S		Central Disc		Baseline	23JUN2015	13:36	N	Double Read
					VISIT 3A	16SEP2015	15:57	N	Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41	N	Double Read
					VISIT 7	14SEP2016	15:36	N	Double Read
					VISIT 8	06SEP2017	15:20	N	Double Read
					VISIT 11	02SEP2020	15:05	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, not treated)	5_S		Cranial Disc, not treated		Baseline	23JUN2015	13:36	N	Double Read
					VISIT 3A	16SEP2015	15:57	N	Double Read
					VISIT 4	02NOV2015	15:31	N	Double Read
					VISIT 6	21MAR2016	15:41	N	Double Read
					VISIT 7	14SEP2016	15:36	N	Double Read
					VISIT 8	06SEP2017	15:20	N	Double Read
					VISIT 11	02SEP2020	15:05	N	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	23JUN2015	13:36	67.98496	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 3A	16SEP2015	15:57	69.16464	Double Read
					VISIT 4	02NOV2015	15:31	68.86112	Double Read
					VISIT 6	21MAR2016	15:41	70.52544	Double Read
					VISIT 7	14SEP2016	15:36	69.69104	Double Read
					VISIT 8	06SEP2017	15:20	71.70272	Double Read
					VISIT 11	02SEP2020	15:05	66.25328	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
T2 (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
T2 (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	23JUN2015	13:36	98.79088	Double Read
					VISIT 3A	16SEP2015	15:57	103.8184	Double Read
					VISIT 4	02NOV2015	15:31	108.38144	Double Read
					VISIT 6	21MAR2016	15:41	103.74032	Double Read
					VISIT 7	14SEP2016	15:36	104.2032	Double Read
					VISIT 8	06SEP2017	15:20	97.21072	Double Read
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	02SEP2020	15:05	105.74928	Double Read
					VISIT 3A	16SEP2015	15:57		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S		Caudal Disc		Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S		Central Disc		Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
					VISIT 11	02SEP2020	15:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 8	06SEP2017	15:20		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S		Caudal Disc		VISIT 11	02SEP2020	15:05		Double Read
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S		Central Disc		Baseline	23JUN2015	13:36	lower	Double Read
					VISIT 3A	16SEP2015	15:57	lower	Double Read
					VISIT 4	02NOV2015	15:31	lower	Double Read
					VISIT 6	21MAR2016	15:41	lower	Double Read
					VISIT 7	14SEP2016	15:36	lower	Double Read
					VISIT 8	06SEP2017	15:20	lower	Double Read
					VISIT 11	02SEP2020	15:05	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S		Caudal Disc		Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S		Central Disc		VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, not treated,)	5_S		Cranial Disc, not treated		Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	23JUN2015	13:36	8.9244844572	Double Read
					VISIT 3A	16SEP2015	15:57	7.0490640394	Double Read
					VISIT 4	02NOV2015	15:31	6.9361916086	Double Read
					VISIT 6	21MAR2016	15:41	9.3597621878	Double Read
					VISIT 7	14SEP2016	15:36	5.5233973161	Double Read
					VISIT 8	06SEP2017	15:20	6.1151690164	Double Read
					VISIT 11	02SEP2020	15:05	4.7301104127	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
T2_error (ms) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	23JUN2015	13:36	5.3184168506	Double Read
					VISIT 3A	16SEP2015	15:57	4.2891116018	Double Read
					VISIT 4	02NOV2015	15:31	2.9896381858	Double Read
					VISIT 6	21MAR2016	15:41	2.0276065907	Double Read
					VISIT 7	14SEP2016	15:36	2.1079531170	Double Read
					VISIT 8	06SEP2017	15:20	4.7459962629	Double Read
					VISIT 11	02SEP2020	15:05	2.1273653813	Double Read
T2_error (ms) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S		Caudal Disc	Anulus Fibrosus	VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S		Caudal Disc	Complete Disc	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S		Caudal Disc	Nucleus Pulposus	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S		Central Disc	Anulus Fibrosus	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	Baseline	23JUN2015	13:36	12515.5	Double Read
					VISIT 3A	16SEP2015	15:57	11615.5	Double Read
					VISIT 4	02NOV2015	15:31	12403.5	Double Read
					VISIT 6	21MAR2016	15:41	11533.5	Double Read
					VISIT 7	14SEP2016	15:36	10540.0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Central Disc, Complete Disc)	5_S		Central Disc	Complete Disc	VISIT 8	06SEP2017	15:20	11824.5	Double Read
					VISIT 11	02SEP2020	15:05	11554.0	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S		Central Disc	Nucleus Pulposus	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
Volume (mm^3) (Cranial Disc, not treated, Anulus Fibrosus)	5_S		Cranial Disc, not treated	Anulus Fibrosus	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read
					VISIT 11	02SEP2020	15:05		Double Read
Volume (mm^3) (Cranial Disc, not treated, Complete Disc)	5_S		Cranial Disc, not treated	Complete Disc	Baseline	23JUN2015	13:36	17267.5	Double Read
					VISIT 3A	16SEP2015	15:57	17620.5	Double Read
					VISIT 4	02NOV2015	15:31	18291.5	Double Read
					VISIT 6	21MAR2016	15:41	17244.0	Double Read
					VISIT 7	14SEP2016	15:36	16701.0	Double Read
					VISIT 8	06SEP2017	15:20	17235.5	Double Read
					VISIT 11	02SEP2020	15:05	17784.0	Double Read
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	Baseline	23JUN2015	13:36		Double Read
					VISIT 3A	16SEP2015	15:57		Double Read
					VISIT 4	02NOV2015	15:31		Double Read
					VISIT 6	21MAR2016	15:41		Double Read
					VISIT 7	14SEP2016	15:36		Double Read
					VISIT 8	06SEP2017	15:20		Double Read

NDisc Study / EudraCT No: 2010-023830-22 Snapshot date: 16NOV2021 TETEC

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1304 Age=33 Sex=Male Actual Treatment=ND basic

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Volume (mm^3) (Cranial Disc, not treated, Nucleus Pulposus)	5_S		Cranial Disc, not treated	Nucleus Pulposus	VISIT 11	02SEP2020	15:05		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1305 Age=47 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Disc degeneration grading (Pfirrmann) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	14OCT2015	13:59		Double Read
Disc degeneration grading (Pfirrmann) (Central Disc)	5_S	4_5	Central Disc		Baseline	14OCT2015	13:59	3	Double Read
Disc degeneration grading (Pfirrmann) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	14OCT2015	13:59	4	Double Read
Distinct sclerosis of the osteochondral endplate (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	14OCT2015	13:59		Double Read
Distinct sclerosis of the osteochondral endplate (Central Disc)	5_S	4_5	Central Disc		Baseline	14OCT2015	13:59	N	Double Read
Distinct sclerosis of the osteochondral endplate (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	14OCT2015	13:59	Y	Double Read
Dorsal disc extrusion (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	14OCT2015	13:59		Double Read
Dorsal disc extrusion (Central Disc)	5_S	4_5	Central Disc		Baseline	14OCT2015	13:59	Y	Double Read
Dorsal disc extrusion (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	14OCT2015	13:59	N	Double Read
Extradiscal fluid collection	5_S	4_5	General		Baseline	14OCT2015	13:59	N	Double Read
Fracture	5_S	4_5	General		Baseline	14OCT2015	13:59	N	Double Read
Height from Volume (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	14OCT2015	13:59		Double Read
Height from Volume (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	14OCT2015	13:59	10.515	Double Read
Height from Volume (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	14OCT2015	13:59	10.515	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1305 Age=47 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Height manual (mm) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	14OCT2015	13:59		Double Read
Height manual (mm) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	14OCT2015	13:59	6.405645	Double Read
Height manual (mm) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	14OCT2015	13:59	5.73887	Double Read
More than moderate degenerative foraminal stenosis right or left (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	14OCT2015	13:59		Double Read
More than moderate degenerative foraminal stenosis right or left (Central Disc)	5_S	4_5	Central Disc		Baseline	14OCT2015	13:59	N	Double Read
More than moderate degenerative foraminal stenosis right or left (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	14OCT2015	13:59	N	Double Read
More than moderate degenerative spinal stenosis (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	14OCT2015	13:59		Double Read
More than moderate degenerative spinal stenosis (Central Disc)	5_S	4_5	Central Disc		Baseline	14OCT2015	13:59	N	Double Read
More than moderate degenerative spinal stenosis (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	14OCT2015	13:59	N	Double Read
Normal lordotic LS	5_S	4_5	General		Baseline	14OCT2015	13:59	Y	Double Read
Osteochondrosis grading (Modic) (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	14OCT2015	13:59		Double Read
Osteochondrosis grading (Modic) (Central Disc)	5_S	4_5	Central Disc		Baseline	14OCT2015	13:59	0	Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1305 Age=47 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
Osteochondrosis grading (Modic) (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	14OCT2015	13:59	1	Double Read
Protruding osteophyte (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	14OCT2015	13:59		Double Read
Protruding osteophyte (Central Disc)	5_S	4_5	Central Disc		Baseline	14OCT2015	13:59	N	Double Read
Protruding osteophyte (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	14OCT2015	13:59	N	Double Read
Relevant scoliosis	5_S	4_5	General		Baseline	14OCT2015	13:59	Y	Double Read
Spondylolisthesis > Meyerding grade I (Caudal Disc)	5_S	4_5	Caudal Disc		Baseline	14OCT2015	13:59		Double Read
Spondylolisthesis > Meyerding grade I (Central Disc)	5_S	4_5	Central Disc		Baseline	14OCT2015	13:59	N	Double Read
Spondylolisthesis > Meyerding grade I (Cranial Disc, add. treated)	5_S	4_5	Cranial Disc, add. treated		Baseline	14OCT2015	13:59	N	Double Read
T2 (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	14OCT2015	13:59		Double Read
T2 (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	14OCT2015	13:59		Double Read
T2 (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	14OCT2015	13:59		Double Read
T2 (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	14OCT2015	13:59		Double Read
T2 (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	14OCT2015	13:59	65.0216	Double Read
T2 (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	14OCT2015	13:59		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1305 Age=47 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	14OCT2015	13:59		Double Read
T2 (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	14OCT2015	13:59	78.22608	Double Read
T2 (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	14OCT2015	13:59		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	14OCT2015	13:59		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Central Disc,)	5_S	4_5	Central Disc		Baseline	14OCT2015	13:59		Double Read
T2 signal in comparison with 2nd examination (3A, before ADCT) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	14OCT2015	13:59		Double Read
T2 signal in comparison with caudal intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	14OCT2015	13:59		Double Read
T2 signal in comparison with caudal intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	14OCT2015	13:59		Double Read
T2 signal in comparison with caudal intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	14OCT2015	13:59		Double Read
T2 signal in comparison with cranial intervertebral disc space (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	14OCT2015	13:59		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1305 Age=47 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2 signal in comparison with cranial intervertebral disc space (Central Disc,)	5_S	4_5	Central Disc		Baseline	14OCT2015	13:59	lower	Double Read
T2 signal in comparison with cranial intervertebral disc space (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	14OCT2015	13:59	lower	Double Read
T2 signal in comparison with pre-examination (2A) (Caudal Disc,)	5_S	4_5	Caudal Disc		Baseline	14OCT2015	13:59		Double Read
T2 signal in comparison with pre-examination (2A) (Central Disc,)	5_S	4_5	Central Disc		Baseline	14OCT2015	13:59		Double Read
T2 signal in comparison with pre-examination (2A) (Cranial Disc, add. treated,)	5_S	4_5	Cranial Disc, add. treated		Baseline	14OCT2015	13:59		Double Read
T2_error (ms) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	14OCT2015	13:59		Double Read
T2_error (ms) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	14OCT2015	13:59		Double Read
T2_error (ms) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	14OCT2015	13:59		Double Read
T2_error (ms) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	14OCT2015	13:59		Double Read
T2_error (ms) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	14OCT2015	13:59	10.8795039918	Double Read
T2_error (ms) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	14OCT2015	13:59		Double Read
T2_error (ms) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	14OCT2015	13:59		Double Read

Listing 16.2.3.4: MRI parameters - all enrolled subjects

Center/Subject=13/1305 Age=47 Sex=Female Actual Treatment=ND plus

Parameter	Central treated Disc	Additional treated Disc	Disc Type	Disc Structure	Visit	Date	Time	Result	Reading process
T2_error (ms) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	14OCT2015	13:59	6.13215559708	Double Read
T2_error (ms) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	14OCT2015	13:59		Double Read
Volume (mm^3) (Caudal Disc, Anulus Fibrosus)	5_S	4_5	Caudal Disc	Anulus Fibrosus	Baseline	14OCT2015	13:59		Double Read
Volume (mm^3) (Caudal Disc, Complete Disc)	5_S	4_5	Caudal Disc	Complete Disc	Baseline	14OCT2015	13:59		Double Read
Volume (mm^3) (Caudal Disc, Nucleus Pulposus)	5_S	4_5	Caudal Disc	Nucleus Pulposus	Baseline	14OCT2015	13:59		Double Read
Volume (mm^3) (Central Disc, Anulus Fibrosus)	5_S	4_5	Central Disc	Anulus Fibrosus	Baseline	14OCT2015	13:59		Double Read
Volume (mm^3) (Central Disc, Complete Disc)	5_S	4_5	Central Disc	Complete Disc	Baseline	14OCT2015	13:59	8420.5	Double Read
Volume (mm^3) (Central Disc, Nucleus Pulposus)	5_S	4_5	Central Disc	Nucleus Pulposus	Baseline	14OCT2015	13:59		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Anulus Fibrosus)	5_S	4_5	Cranial Disc, add. treated	Anulus Fibrosus	Baseline	14OCT2015	13:59		Double Read
Volume (mm^3) (Cranial Disc, add. treated, Complete Disc)	5_S	4_5	Cranial Disc, add. treated	Complete Disc	Baseline	14OCT2015	13:59	8635.0	Double Read
Volume (mm^3) (Cranial Disc, add. treated, Nucleus Pulposus)	5_S	4_5	Cranial Disc, add. treated	Nucleus Pulposus	Baseline	14OCT2015	13:59		Double Read

Listing 16.2.3.5: Unscheduled Visits - Anamnesis - all enrolled subjects

Site/ SubjectID	Treatment group	Newly developed transversal symptoms	Newly developed neurological symptoms	Fever accomp. with back pain	Local percussion tenderness	Persisting back pain > 7 d	Back pain with no response to medication	Other
01/0113	ND basic			No	No	No	No	Yes / radiculopathy
	ND basic			No	No	No	No	Yes / REHERNIATION
	ND basic		Lumbago	No	No	No	Yes	No
	ND basic	Back pain		No	No	Yes	Yes	No
01/0118	ND plus	S1 RADICULOPATHY LEFT		No	No	No	No	Yes / S1 RADICULOPATHY LEFT
	ND plus			No	No	Yes	Yes	Yes / S1 RADICULOPATHY LEFT
	ND plus			No	No	No	No	Yes / 1 week after sequestrectomy S1 radiculopathy + hypaesthesia (left foot) reappeared
	ND plus			No	No	Yes	No	Yes / S1 radicular pain without motoric deficite
	ND plus			No	No	Yes	Yes	No
	ND plus			No	No	No	No	Yes / NEUROPATHIC PAIN
	ND plus	neuropathic pain		No	No	Yes	Yes	No
	ND plus	neuropathic SM-radicular pain	low-back-pain	No	No	Yes	No	No
01/0119	ND basic			No	Yes	No	No	Yes / lumbago
01/0122	ND plus			No	No	Yes	Yes	Yes / RADICULOPATHY L3 right
01/0123	ND plus	Numbness according to nerve route distribution area C7	motor deficit 4/5	No	No	Yes	Yes	No
	ND plus			No	No	Yes	Yes	No
	ND plus			No	No	No	No	No
	ND plus	radicular pain		No	No	No	No	No
	ND plus			No	No	Yes	Yes	No
01/0125	SC		Lumbago	No	No	Yes	No	No
01/0126	ND basic			No	No	No	No	Yes / LUMBOISCHAGIA L4/L5
01/0127	ND plus		Radiculopathy S1	No	No	Yes	No	No
	ND plus		Pain	No	No	Yes	No	No

Listing 16.2.3.5: Unscheduled Visits - Anamnesis - all enrolled subjects

Site/ SubjectID	Treatment group	Newly developed transversal symptoms	Newly developed neurological symptoms	Fever accomp. with back pain	Local percussion tenderness	Persisting back pain > 7 d	Back pain with no response to medication	Other
01/0128	ND plus	lumbalgia		No	Yes	Yes	Yes	No
	ND plus	numbness right leg		No	Yes	Yes	Yes	No
01/0129	SC	radicular pain L5	progredient palsy	No	No	Yes	Yes	No
	SC	hypoesthesia	progredient palsy	No	No	Yes	Yes	No
	SC	radicular pain L5	progredient palsy	No	No	Yes	Yes	No
	SC	hypesthesia	progredient palsy	No	No	Yes	Yes	No
01/0133	ND plus	RADICULOPATHY		No	No	No	No	No
01/0134	ND basic			No	No	No	No	Yes / Bursitis trochanterica
01/0136	ND basic			No	No	No	No	Yes / RADICULOPATHY L3 right
01/0139	ND plus			No	No	No	No	Yes / RADICULOPATHY S1 RIGHT
01/0141	SC			No	No	No	No	No
01/0144	ND basic	radicular pain S1	none	No	No	Yes	No	No
	ND basic	persisting radicular pain S1 left		No	No	Yes	No	No
	ND basic	tingling paresthesia S1 left		No	No	Yes	No	No
01/0145	ND plus			No	No	No	No	Yes / SACROILIACAL JOINT PAIN RIGHT
01/0148	ND plus		Lumbago	No	No	Yes	No	No
01/0153	ND basic			No	Yes	Yes	Yes	Yes / LUMBAGO
	ND basic			No	No	No	No	No
	ND basic		S1 radicular pain	No	No	Yes	No	No
02/0201	ND plus	Hypoesthesia lat. L5 right		No				
	ND plus	paresis foot right (4/5)		No				

Listing 16.2.3.5: Unscheduled Visits - Anamnesis - all enrolled subjects

Site/ SubjectID	Treatment group	Newly developed transversal symptoms	Newly developed neurological symptoms	Fever accomp. with back pain	Local percussion tenderness	Persisting back pain > 7 d	Back pain with no response to medication	Other
02/0203	ND basic		Pain in the right ISA	No	Yes	No	Yes	Yes / Pain in ISA. Katadolon and didn't help
	ND basic		VAS Pain 8-9/10	No	Yes	Yes	Yes	No
	ND basic			No	No	Yes	No	No
	ND basic			No	No	Yes	No	
	ND basic			No	No	Yes	No	
02/0208	ND plus	hypesthaesia S1 lefts		No	Yes	No	No	Yes / left side L5/S1 paravertebral
	ND plus		rezidiv prolaps	No	No	Yes	No	No
	ND plus			No	No	Yes	Yes	No
	ND plus			No	No	Yes	No	No
02/0209	ND plus		Pain left leg, ae. pseudoradicular	No	No	No	No	No
02/0216	ND plus		permanent pain	No	No	Yes	Yes	No
	ND plus			No	No	Yes	Yes	No
06/0607	ND plus			No	No	Yes	No	No
06/0610	ND plus	L5/S1 pain		No	Yes	Yes	No	No
	ND plus	L5/S1 numbness		No	Yes	Yes	No	No
06/0612	ND plus			No	No	No	No	No
	ND plus			No	No	Yes	No	No
06/0614	ND plus	Increase in dysaesthesia S1 right	Increase lumboischialgia right with predominantly facet syndrom L5/S1 right	No	Yes	Yes	No	Yes / Load dependent increase in Lumbago
	ND plus	Numbness S1 right		No	Yes	Yes	No	No
	ND plus	Dysaesthesia S1 right		No	Yes	Yes	No	No
	ND plus	Pain S1 right		No	Yes	Yes	No	No
	ND plus	hypoesthesia S1 right		No	Yes	Yes	No	Yes / paraesthesia right S1 lower leg and foot

Listing 16.2.3.5: Unscheduled Visits - Anamnesis - all enrolled subjects

Site/ SubjectID	Treatment group	Newly developed transversal symptoms	Newly developed neurological symptoms	Fever accomp. with back pain	Local percussion tenderness	Persisting back pain > 7 d	Back pain with no response to medication	Other
06/0614	ND plus	Ischialgia S1 right		No	Yes	Yes	No	Yes / paraesthesia right S1 lower leg and foot / paraesthesia right S1 lower leg and foot
	ND plus	Hypoesthesia S1 right side		No	Yes	Yes	No	Yes / paraesthesia right S1 lower leg and foot
	ND plus	sciatica S1 right side		No	Yes	Yes	No	Yes / paraesthesia right S1 lower leg and foot / paraesthesia right S1 lower leg and foot
	ND plus			No		Yes	No	No
08/0802	ND plus	None	Neck Pain	NA	NA	NA	NA	NA
	ND plus	None	Shoulder Pain	NA	NA	NA	NA	NA
	ND plus	None	Pain left arm	NA	NA	NA	NA	NA
08/0805	ND basic	Radiculopathy L3 right		No	Yes	Yes	No	
	ND basic			No	No	No	No	No
08/0807	ND plus	None	Leg pain right > left	No	Yes	No	No	No
09/0905	ND plus	Hip flexian,	sciatica L4 right side	No	No	No	No	No
	ND plus	knee extension and foot	sciatica L4 right side	No	No	No	No	No
	ND plus	extension weakness kg 4/5	sciatica L4 right side	No	No	No	No	No
	ND plus	mostly due to pain right side	sciatica L4 right side	No	No	No	No	No
	ND plus	Lasegue is still positive on the right	Since Sept. 18 right leg pain up to the lateral thigh/knee joint	No	Yes	Yes	No	No
	ND plus	Force hip flexion right 5/5	PRT L4 right with pain retrieve	No	Yes	Yes	No	No
	ND plus	nonsensory deficit	Patient still needs tilidine 100/8 mg 1-0-1 every day	No	Yes	Yes	No	No

Listing 16.2.3.5: Unscheduled Visits - Anamnesis - all enrolled subjects

Site/ SubjectID	Treatment group	Newly developed transversal symptoms	Newly developed neurological symptoms	Fever accomp. with back pain	Local percussion tenderness	Persisting back pain > 7 d	Back pain with no response to medication	Other
09/0905	ND plus	Hyperalgesia tight lateral thigh	Patient still needs tilidine 100/8 mg 1-0-1 every day	No	Yes	Yes	No	No
09/0909	ND plus			No	No	No	No	Yes / Since 6 Days Lumbogluteal and Hipp-Pain Left
09/0913	ND basic		acute low back pain without radicular symptoms	No	Yes	No	No	No
09/0915	ND basic		low back pain	No	Yes	Yes	No	No
	ND basic	subjective weakness of the foot, not objectifiable	Pain radiating for about 2 weeks from the buttocks to the calf on the right / L5 radiculopathie right	No	No	Yes	No	No
11/1101	ND plus	paresis of plantor flexion KG 2	Lumboischialgia leftsided	No	No	No	No	No
	ND plus	missing ankle reflex leftsided	Lumboischialgia leftsided	No	No	No	No	No
	ND plus	Numbness leftsided	Lumboischialgia leftsided	No	No	No	No	No
	ND plus	Hypersensitive leftsided	Lumboischialgia leftsided	No	No	No	No	No
	ND plus	hypesthesia left sole foot	Strong lumboischialgien (NRS 8/10) radialing in the dorsolateral thigh, the dorsal lower leg and the inside of the foot left side	No	No	Yes	Yes	No

Listing 16.2.3.5: Unscheduled Visits - Anamnesis - all enrolled subjects

Site/ SubjectID	Treatment group	Newly developed transversal symptoms	Newly developed neurological symptoms	Fever accomp. with back pain	Local percussion tenderness	Persisting back pain > 7 d	Back pain with no response to medication	Other
11/1101	ND plus	hip flexor left paresis 4/5	Strong lumboischialgien (NRS 8/10) radialing in the dorsolateral thigh, the dorsal lower leg and the inside of the foot left side	No	No	Yes	Yes	No
	ND plus	foot extensor paresis left 4/5	Strong lumboischialgien (NRS 8/10) radialing in the dorsolateral thigh, the dorsal lower leg and the inside of the foot left side	No	No	Yes	Yes	No
	ND plus	Foot lifter paresis left 4/5	Strong lumboischialgien (NRS 8/10) radialing in the dorsolateral thigh, the dorsal lower leg and the inside of the foot left side	No	No	Yes	Yes	No
	ND plus	foot lowering paresis left 4/5	Strong lumboischialgien (NRS 8/10) radialing in the dorsolateral thigh, the dorsal lower leg and the inside of the foot left side	No	No	Yes	Yes	No
	ND plus							

Listing 16.2.3.5: Unscheduled Visits - Anamnesis - all enrolled subjects

Site/ SubjectID	Treatment group	Newly developed transversal symptoms	Newly developed neurological symptoms	Fever accomp. with back pain	Local percussion tenderness	Persisting back pain > 7 d	Back pain with no response to medication	Other
11/1103	SC	paresis of plantarflexion KG3 left sided		No	No	Yes	Yes	No
	SC	missing ankle reflex left sided		No	No	Yes	Yes	No
	SC	tingle-dysesthesia left		No	No	Yes	Yes	No
	SC	paresis of planterflexions KG 3 left sided		No	No	Yes	Yes	No
12/1201	ND plus			No	No	No	No	No
	ND plus	pain lumbal + upper leg left		No	No	No	No	No
	ND plus			No	No	Yes	Yes	No
	ND plus			No	Yes	Yes	No	No
	ND plus	paraesthesia upper leg left		No	No	Yes	No	No
13/1301	ND plus	intermediate dizziness		No	Yes	No	No	Yes / extension of pain to dermatome S1
	ND plus	persistant hyperaesthesia in right leg		No	No	Yes	Yes	No
13/1303	SC		Hyperaesthesia foot right	No	Yes	No	No	No
	SC		Hyperaesthesia buttock right	No	Yes	No	No	No
	SC		Hyperaesthesia thigh right	No	Yes	No	No	No
	SC		muscle hardening right thigh backw.	No	No	No	No	No
	SC		disturbing sensation calf right	No	No	No	No	No
	SC		slight pain right thigh backwards	No	No	No	No	No

Listing 16.2.3.5: Unscheduled Visits - Anamnesis - all enrolled subjects

Site/ SubjectID	Treatment group	Newly developed transversal symptoms	Newly developed neurological symptoms	Fever accomp. with back pain	Local percussion tenderness	Persisting back pain > 7 d	Back pain with no response to medication	Other
13/1303	SC		no lumbago/sciatic pain syndrome	No	No	No	No	No
13/1304	ND basic			No	No	No	No	No
	ND basic			No	No	No	No	No
	ND basic	none	sensation in thigh left	No	No	No	No	No
	ND basic			No	No	No	No	No

Listing 16.2.3.6: Unscheduled Visits - Repeating Surgery - all enrolled subjects

Site/ SubjectID	Treatment group	Type of degenerative lumbar disc	Date of procedure	Start/ End time	Location	Procedures performed	Use of micro scope intra- operative ?	Blood content within operative situs (ml)	Technique being used for haemostasis	Description of removed sequester
01/0112	ND basic	HD	03APR2013	11:20 / 12:30	L5/S1/Right	Sequestrectomy	Yes	UN	Bipolar epidural coagulation	
01/0113	ND basic	HD	04AUG2014	12:04 / 13:20	L5/S1/Left	Other/ partial nucleotomy	Yes	150	Bipolar epidural coagulation	Tight fitting sequester
			03OCT2014	12:02 / 15:42	L5/S1/Right	Other/ SPONDYLODESIS	Yes	450	Bipolar epidural coagulation	Other / INFECTIOUS
01/0118	ND plus	HD	17JAN2018	10:04 / 11:22	L5/S1/Left	Other/ implantation of spinal cord stimulator	No	UNK	Bipolar epidural coagulation	
01/0123	ND plus	HD	25MAY2018	08:26 / 10:27	L4/L5/Right	Sequestrectomy	No	UNK		
			25MAY2018	08:26 / 10:27	L3/L4/Right	Sequestrectomy	No	UNK		
01/0126	ND basic	HD	09MAR2015	13:40 / 14:45	L4/L5/Left	Sequestrectomy	Yes	050	Sponge and Bipolar epidural coagulation	Loose sequester
01/0129	SC	HD	20MAR2019	12:36 / 13:48	L4/L5/Right	Other/ Recessotomy	No	UNK	Bipolar epidural coagulation	
01/0133	ND plus	HD	30DEC2014	13:40 / 15:05	L4/L5/Left	Other/ Sequestrectomy, DECOMPRESSION, MICRODISCECTOMY	Yes	UNK	Sponge and Bipolar epidural coagulation	Other / UNKNOWN
02/0201	ND plus	ADD	29DEC2015	10:10 / 11:15	L4/L5/Right	Sequestrectomy	Yes	0	Bipolar epidural coagulation	Tight fitting sequester
02/0208	ND plus	ADD	19DEC2013	11:00 / 11:30	L5/S1/Left	Other/ Periradicular infiltration				
			02APR2014		L5/S1/Left	Sequestrectomy		UNK		
			22SEP2015	11:27 / 12:15	L5/S1/Left	Sequestrectomy	Yes	UNK	Bipolar epidural coagulation	Fibrousness tissue

Listing 16.2.3.6: Unscheduled Visits - Repeating Surgery - all enrolled subjects

Site/ SubjectID	Treatment group	Type of degenerative lumbar disc	Date of procedure	Start/ End time	Location	Procedures performed	Use of micro scope ? ?	Blood content within intra- operative situs (ml)	Technique being used for haemostasis	Description of removed sequester
06/0610	ND plus	ADD	20JAN2016	15:13 / 16:35	L5/S1/Left	Other/ Nucleotomy, Neurolysis S1 left	Yes	050	Bipolar epidural coagulation	Tight fitting sequester
06/0614	ND plus	ADD	22FEB2016	UNK / UNK	L5/S1/Right	Other/ Infiltration L5/S1 facet joint right and ISG right	No			
			11MAR2016	08:33 / 10:05	L5/S1/Right	Other/ Nucleotomie right	Yes	050	Sponge and Bipolar epidural coagulation	Tight fitting sequester
			11MAR2016	08:33 / 10:05	L4/L5/Right	Other/ Nucleotomie right	Yes	050	Sponge and Bipolar epidural coagulation	Tight fitting sequester
			11AUG2016	10:26 / 14:44	L5/S1/Right	Other/ PLIF L5/S1, TLIF L4/L5	Yes	200	Sponge and Bipolar epidural coagulation	Compact tissue
			11AUG2016	10:26 / 14:44	L4/L5/Right	Other/ PLIF L5/S1, TLIF L4/L5	Yes	200	Sponge and Bipolar epidural coagulation	Compact tissue
08/0805	ND basic	HD	28JUL2016	14:16 / 15:40	L2/L3/Right	Other/ Nucleotomy	Yes	40	Bipolar epidural coagulation	Loose sequester
09/0905	ND plus	HD	11MAR2019	13:50 / 15:20	L4/L5/Right	Sequestrectomy	Yes	150	Sponge and Bipolar epidural coagulation	Fibrousness tissue
11/1101	ND plus	ADD	27SEP2017	08:30 / 09:25	L5/S1/Left	Sequestrectomy	Yes	050	Bipolar epidural coagulation	Compact tissue
			31JUL2019	08:44 / 11:32	L5/S1/Left	Other/ TLIF L5/S1 Post. Instrumentation	Yes	250	Bipolar epidural coagulation	Tight fitting sequester
11/1103	SC	HD	05JAN2018	14:45 / 16:03	L5/S1/Left	Sequestrectomy	Yes	50	Bipolar epidural coagulation	Fibrousness tissue
			10JAN2018	18:20 / 19:20	L5/S1/Left	Sequestrectomy	Yes	56	Bipolar epidural coagulation	Loose sequester